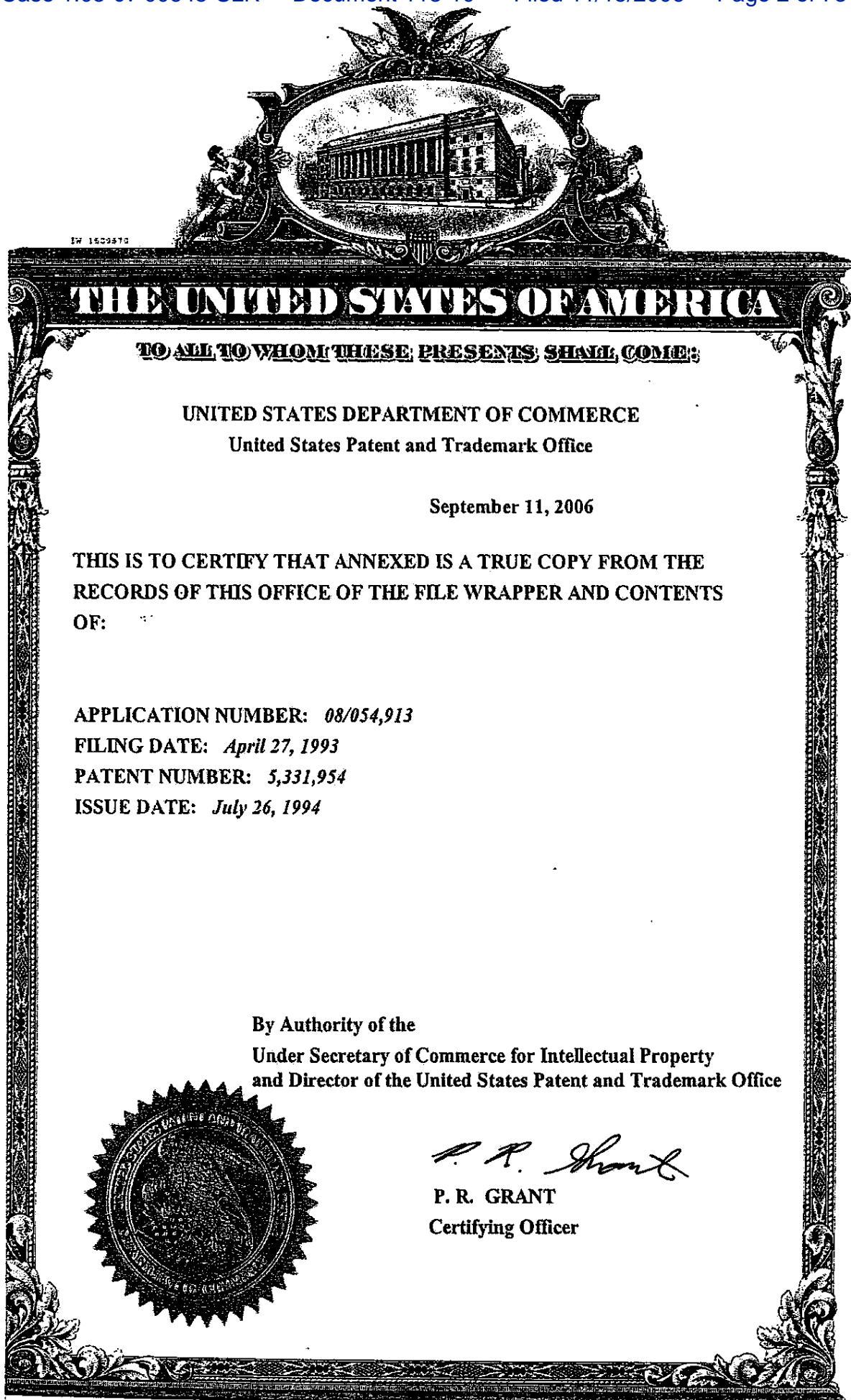


EXHIBIT 12



128-200 128-200		Class		Subclass		ISSUE CLASSIFICATION		[REDACTED]		(18)																					
UTILITY SERIAL NUMBER		/054913		PATENT DATE JUL 26 1994		PATENT NUMBER																									
SERIAL NUMBER 08/054,913		FILING DATE 04/27/93		CLASS 128		SUBCLASS 300 33		GROUP ART UNIT 3307		5331954																					
APPLICANT: JORN REX, ROSKILDE, DENMARK; KIM STEENGAARD, HVIDOVRE, DENMARK; SVEND ELK, BIRKEROD, DENMARK.																															
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<table border="1"> <tr> <td>Foreign priority claimed 35 USC 119 conditions met</td> <td><input checked="" type="checkbox"/> yes <input type="checkbox"/> no</td> <td><input type="checkbox"/> yes <input checked="" type="checkbox"/> no</td> <td>AS FILED</td> <td>STATE OR COUNTRY</td> <td>SHEETS DRWGS.</td> <td>TOTAL CLAIMS</td> <td>INDEP. CLAIMS</td> <td>FILING FEE RECEIVED</td> <td>ATTORNEY'S DOCKET NO.</td> </tr> <tr> <td>Verified and Acknowledged</td> <td colspan="2">Examiner's Initials</td> <td>→</td> <td>DKX</td> <td>2</td> <td>16</td> <td>1</td> <td>\$940.00</td> <td>3573.214US</td> </tr> </table>												Foreign priority claimed 35 USC 119 conditions met	<input checked="" type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input checked="" type="checkbox"/> no	AS FILED	STATE OR COUNTRY	SHEETS DRWGS.	TOTAL CLAIMS	INDEP. CLAIMS	FILING FEE RECEIVED	ATTORNEY'S DOCKET NO.	Verified and Acknowledged	Examiner's Initials		→	DKX	2	16	1	\$940.00	3573.214US
Foreign priority claimed 35 USC 119 conditions met	<input checked="" type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input checked="" type="checkbox"/> no	AS FILED	STATE OR COUNTRY	SHEETS DRWGS.	TOTAL CLAIMS	INDEP. CLAIMS	FILING FEE RECEIVED	ATTORNEY'S DOCKET NO.																						
Verified and Acknowledged	Examiner's Initials		→	DKX	2	16	1	\$940.00	3573.214US																						
ADDRESS: STEVE T. ZELSON NOVO NORDISK OF NORTH AMERICA, INC. 405 LEXINGTON AVENUE, STE. 6200 NEW YORK, NY 10174-6201																															
TITLE: DEVICE FOR NASAL DELIVERY OF LIQUID MEDICATIONS																															
U.S. DEPT. of COMM., Pat. & TM Office — PTO-436L (rev. 10-78)																															
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Assistant Examiner: KIMBERLY L. ASHER																															
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Primary Examiner: EDGAR S. BURR S.P.E. GROUP ART UNIT 337																															
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Form PTO-436A
Rev. 5/92

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SERIAL NUMBER 077793,412		FILING DATE 01/13/92	CLASS 239 128	SUBCLASS 200.14	GROUP ART UNIT 3104 3307	EXAMINER K.L. Asher
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APPLICANTS JORN REX, ROSKILDE, DENMARK; KIM STEENGAARD, HVIDOVRE, DENMARK; SVEND ELK, BIRKERØED, DENMARK.

****CONTINUING DATA*******
 VERIFIED
none KA

****FOREIGN/PCT APPLICATIONS*******
 VERIFIED DENMARK 3028/90 12/21/90
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Foreign priority claimed 35 USC 119 conditions met	<input checked="" type="checkbox"/> yes <input type="checkbox"/> no	AS FILED	STATE OR COUNTRY DKX	SHEETS DRGWS. 2	TOTAL CLAIMS 16	INDEP. CLAIMS 1	FILING FEE RECEIVED \$1,140.00	ATTORNEY'S DOCKET NO. 3573.204-US
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Verified and Acknowledged KA Examiner's Initials


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TITLE PEN SHAPED DEVICE FOR NASAL ADMINISTRATION OF DOSES OF A LIQUID MEDICINE

U.S. DEPT. of COMM. Pat. & TM Office - PTO-436L (rev. 10-78)

BAR CODE LABEL						U.S. PATENT APPLICATION	
SERIAL NUMBER		FILING DATE		CLASS		GROUP ART UNIT	
08/054,913		04/27/93		128		3307	
APPLICANT	JORN R. ROSKILDE, DENMARK, DENMARK; KIM STEENGAARD, HVIDOVRE, DENMARK; SVEND ELK, BIRKERØED, DENMARK.						
	CONTINUING DATA*** VERIFIED THIS APPLN IS A CON OF 07/793,412 01/13/92						
	FOREIGN/PCT APPLICATIONS*** VERIFIED PCT PCT/DK91/00400 12/19/91 DENMARK 3028/90 12/21/90						
STATE OR COUNTRY	SHEETS DRAWING	TOTAL CLAIMS	INDEPENDENT CLAIMS	FILING FEE RECEIVED	ATTORNEY DOCKET NO.		
DKX	2	16	1	\$ 940.00	3573.214US		
ADDRESS	STEVE T. ZELSON NOVO NORDISK OF NORTH AMERICA, INC. 405 LEXINGTON AVENUE, STE. 6200 NEW YORK, NY 10174-6201						
	TITLE NOSE PEN						
This is to certify that annexed hereto is a true copy from the records of the United States Patent and Trademark Office of the application as filed which is identified above. By authority of the COMMISSIONER OF PATENTS AND TRADEMARKS							
Date		Certifying Officer					

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BAR CODE LABEL						U.S. PATENT APPLICATION	
SERIAL NUMBER		FILING DATE		CLASS	GROUP ART UNIT		
07/793,412		01/13/92		239	3104		
APPLICANT	JORN REX, ROSKILDE, DENMARK; KIM STEENGAARD, HVIDOVRE, DENMARK; SVEND ELK, BIRKERØD, DENMARK. **CONTINUING DATA***** VERIFIED <hr/> **FOREIGN/PCT APPLICATIONS***** VERIFIED DENMARK 3028/90 12/21/90 <hr/>						
STATE OR COUNTRY	SHEETS DRAWING	TOTAL CLAIMS	INDEPENDENT CLAIMS	FILING FEE RECEIVED	ATTORNEY DOCKET NO.		
DKX	2	16	1	\$1,140.00	3573.204-US		
ADDRESS	STEVE T. ZELSON NOVO NORDISK OF NORTH AMERICA, INC. 405 LEXINGTON AVE., SUITE 6200 NEW YORK, NY 10017						
TITLE	PEN SHAPED DEVICE FOR NASAL ADMINISTRATION OF DOSES OF A LIQUID MEDICINE						
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07/793412

PATENT APPLICATION SERIAL NO. _____

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE
FEE RECORD SHEET

P 30096 01/24/92 07793412
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14-1447 030 960
14-1447 030 968

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220.00CH

PATENT APPLICATION SERIAL NO ~~00~~/054913

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE
FEE RECORD SHEET

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A PEN SHAPED DEVICE FOR NASAL ADMINISTRATION OF DOSES
OF A LIQUID MEDICINE

The invention concerns a dispensing device for dispensing dosed quantities of a fluid medicine as an aerosol, e.g. insulin, to be assimilated through the nasal mucous membranes.

5 Many sorts of medicine are not appropriate for being orally consumed as they are destroyed very quickly in the alimentary canal. Such medicines, therefore, have to be injected to be directly assimilated in the blood.

When such medicines have to be taken frequently through a long period or even the life long as it is the case with, e.g. insulin for diabetics, the wish
10 for a method of taking the medicines without frequent injections occurs. Here the assimilation through the nasal mucous membranes is seen as a solution.

From European Patent Application No. 308,100 is known a dispensing apparatus for dispensing metered quantities of pressurized fluid and in particular for nasal administration of insulin.

15 EP 308,100 meets the wishes for a device which may be used for nasal administration of e.g. insulin, as an activation of the device releases a metered quantity of liquid. However, the amount of liquid released by each activation is preset by the manufacturer of the spray valve, and if a bigger dose than this preset one is wanted, the device must be activated repetitively until the wanted dose is dispensed.

20 The use of a propellant gas as in EP 308,100 is undesirable for more reasons. First of all, precaution should be taken to assure that the propellant gas is kept out of contact with the medicine. Further, the content of sufficient propellant gas to dispense the total content of medicine involves the risk that an overdose is dispensed if the metering valve fails. Finally, as the device is intended to be
25 disposed of when the medicine content is used up, it is against the ^{current trend} time-spirit to use disposable devices containing propellant gases.

Consequently, it is the object of the invention to provide a dispensing apparatus for nasal administration of medicine such as insulin in preset doses without the use of a propellant gas. Another object is to provide a device which has

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the same neutral pen shape as the known pen syringes for subcutaneous injection of insulin.

This is obtained by a device for nasal administration of a number of measured doses of a liquid medicine, especially insulin, comprising a first and a
 5 second housing element coupled together to allow rotation but no axial displacement of the first housing element with respect to the second housing element, said first housing element comprising a cartridge containing the liquid and being sealed by a piston at the end coupled to the second housing element and being at its other end closed by a valve to communicate the liquid in the cartridge with a spray nozzle
 10 when opened, the device according to the invention being characterized in that it further comprises a threaded piston rod engaging the piston of the cartridge ~~un-irrotationally~~ ^{irrotationally} with respect to the first housing element and disposed in the second housing element to move axially therein, a nut element mounted ~~unrotatably~~ ^{irrotationally} but axially displaceably in the second housing element and engaging the thread of the
 15 piston rod, a helical spring abutting at its one end an internal annular abutment on the second housing element and at its other end a shoulder on the nut element to press this nut element and thereby the piston rod and the piston in the directions towards the outlet end of the cartridge setting the liquid therein under pressure to be released by opening the valve for spraying out a dose of the liquid, the housing
 20 elements, the rod, and the nut cooperating so that relative rotation between the housing elements in a selected direction causes relative rotation between the rod and the nut element making the nut element move axially in the second housing element in a direction to compress the helical spring.

The device according to the invention further provides a dispenser
 25 which will work in all positions and in which the liquid remains sterile as no unclean air is to replace the liquid removed from the cartridge during the spraying.

According to the invention, the piston rod may be snap locked into the piston preventing a possible vacuum, which may emerge in the cartridge, from drawing the piston into the cartridge leaving an axial play between the piston rod
 30 and the piston.

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b To ensure that the liquid will hit the part of the nasal mucous membrane which is effective in assimilating the medicine, the nozzle is appropriately made to spray out the liquid at an angle of 0-30° defining the spray as ranging from a jet spray to a fan shaped spray.

5 The nut element may define at least one radially protruding axially extending projection on an exterior portion thereof, and this projection or these projections may be received in one or more corresponding axially extending groove or grooves in an inner portion of the second housing element thereby providing a coupling between this housing element and the nut element ensuring that the nut
10 element may be rotated with the second housing element and be axially displaced in this housing element.

A stop may be provided limiting the axial movement of the nut element into the second housing element, thus limiting the loading of the device to a set maximum dose.

15 Also the movement of the nut element along the piston rod may be limited to avoid setting a larger dose than actually remains in the cartridge.

In a preferred embodiment of the invention, the device has a removable protective cap configured to receive the first housing element and abutting when mounted there on the second housing element; and means for releasably coupling
20 the protective cap and the first housing element for rotation together, so that rotation of the protective cap with respect to the second housing element causes rotation of the first housing element with respect to the second housing element.

The abutting edges of the second housing element and the protective cap may comprise pointing means and scale means, respectively, to measure the
25 relative rotation of the protective cap, and thereby the first housing element, with respect to the second housing element. The displacement of the nut element is proportional to this relative rotation and the measuring of the relative rotation consequently is a measuring of the set dose.

Means may be provided for providing detents at selected rotational
30 positions of the first housing element with respect to the second housing element making the extend of the relative rotation hearable, tactile, and visible as a click is

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heard and a resistance variation is felt each time a detent is passed during the relative rotation the size of which may be seen from the relative position of the pointing means and the scale.

The coupling means for coupling the protective cap to the first housing element may allow the protective cap to receive the first housing element in multiple different angular positions of the protective cap with respect to the first housing element to allow the protective cap to be oriented at a selected position with respect to the second housing element, regardless of the detent rotational position of the first housing element in the second housing element. This way it is always possible to mount the protective cap in position with the "O" of its scale in line with the pointing means on the second housing element.

By the abutting edges having interlocking means for defining a selected angular position of the protective cap with respect to the second housing element it may be ensured that the cap is mounted in its O-position when the pen is stored away after use. The interlocking means may appropriately comprise a recess on the abutting edge of the protective cap and a projection on the abutting edge of the second housing element, the projection being shaped to fit into the recess to define the selected position.

In a preferred embodiment of the device according to the invention, the piston rod is made ^{irrotational} ~~unrotatable~~ by fitting through an opening in an anti-rotation disc, the opening being circular with at least one projection protruding into the opening, by the piston rod having a corresponding profile with recesses corresponding to the projections, and by the anti-rotary disc being at its periphery provided with alternating spaces and teeth fitting into a castellated end of the first housing element. Further, the anti-rotary disc serves as an abutment for the nut element limiting the movement of this element towards the cartridge.

The abutting faces of the nut element and the anti-rotary disc are shaped as annular ramps which when in mutual abutment allow only relative rotation of the first and second housing elements in a device loading direction. Thereby it is precluded that a relative rotation in a direction to unload the device to annul a set dose is continued when the device is unloaded. Such a continued relative rotation

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could draw the piston rod free of the piston and provide an axial play which would undermine the correct dosing.

In a preferred embodiment, the nut element may have a tubular extension coaxially surrounding the piston rod and terminated by a knob at the outer end of the second housing element, this knob being flush with the edge of this outer end, when the annular ramps of the anti-rotary disc and the nut member are in a mutual abutment giving a tactile and visible indication whether the device is loaded or not.

In the following the invention is specified in further detail with reference 10 to the drawing in which

- Fig. 1 shows a plan view of a dispenser according to the invention,
- Fig. 2 shows a plan view of the protective cap,
- Fig. 3 shows a sectional view along the line III-III in Fig. 1, but without the piston rod,
- Fig. 4 shows an enlarged plan view of the anti-rotary disc,
- Fig. 5 shows a side view of the disc in Fig. 4.
- Fig. 6 shows an enlarged detail of the abutting edges of the protective cap and the second housing element in dose setting position, and
- Fig. 7 shows the detail of Fig. 6 in closed position for storing.

Fig. 1 shows a pen shaped device having a first housing element 1 and a second housing element 2 snapped together by an external bead 3, and the first housing element 1 being snapped into an annular groove 4 in the second housing element 2 permitting the two housing elements to be rotated in relation to each other about the common length axis, but not to be displaced in relation to each other along this axis.

The first housing element 1 forms a cartridge for a liquid medicine and is at its one end provided with a neck forming a valve chamber 5 communicating at its one end with the housing element and being at its other end closed by a valve block 6 fitting into an annular sealing 7 fitted to the valve chamber 5 by a ferrule 8.

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The valve block has radial ducts 9 leading to a central bore 10 and being at the outer ends sealed by the inner cylindric surface of the annular sealing 7 when the valve is closed. An inner element 11 of a spray nozzle has a rod fitting into the bore 10 with a small clearance leaving a duct leading to a spray nozzle 12 in a nozzle 5 element 13 surrounding the inner element 11 leaving a fine duct from the bore 10 to the nozzle 12.

The nozzle element 13 is provided with a tubular central part 14 fitting over the part with the bore 10. An internal annular bead 15 in the part 14 is lodged in an annular groove 16 in the part with the central bore.

10 The nozzle element 13 further comprises a skirt 17 surrounding at some distance the tubular central part 14 and being at its edge snapped on the neck 18 of a release member 19 fitting over the outer end of the cartridge, the neck 18 of the release member 19 being so much shorter than the neck of the cartridge that it may be axially displaced along the neck of the cartridge limited by its outer 15 end abutting the ferrule or by its shoulder abutting the shoulder of the cartridge.

The nozzle element and release member 19 are kept in their position with the neck 18 of the release member 19 abutting the ferrule 8 by a helical spring 20 surrounding the central part 14 of the nozzle element 13 abutting at its one end the ferrule 8 and at its other end a contact face between the central part 14 and the 20 skirt 17 of the nozzle element 13. In this position the radial ducts 9 lie opposite the sealing 7 and the valve is closed. When the release member 19 is displaced in its axial direction to bring its internal shoulders in abutment with the outer shoulders of the cartridge, the radial ducts 9 are passed past the sealing 7 and into the valve chamber 5 and a communication between the liquid in the cartridge is established 25 through the chamber 5, the radial ducts 9, the bore 10 and the clearance between the inner element 11 and the nozzle element 13 to the spray nozzle 12. This way the liquid in the cartridge will be sprayed out through the nozzle 12 when set under pressure as described below.

The pressure in the cartridge is provided by exerting upon a piston 21, 30 which closes the end of the cartridge opposite the neck, a force trying to force this piston into the cartridge. A sealing element, which here is shown as an O-ring

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mounted in a circumferential groove in the piston, provides a sealing between the piston and the cartridge wall.

10 A piston rod 22 engaging the piston 21 protrudes through an anti rotary disc 23 mounted at the end of the first housing element 1 to make the piston rod 22 ^{irrotational} ~~unrotatable~~ in relation to this housing element.

This may be obtained by the disc, as shown in Figs. 4 and 5 having spaced teeth 42 along its periphery fitting into a castellated end of the first housing element and by the piston rod having a non-circular profile fitting into a corresponding central opening in the disc. The piston rod is a mainly cylindric, threaded rod 10 having diametrically opposite axial recesses 25 engaged by corresponding diametrically opposite projections 26 in the mainly circular opening of the anti-rotary disc.

The mainly cylindric piston rod 22 is threaded and is surrounded by a nut element 27 having at its end facing and abutting the anti-rotary disc a short 15 internal thread 28, the rest of the inner surface of the nut element 27 being smooth fitting over the threaded piston rod to guide this rod in its axial movement. The nut element has at its threaded end external axial ribs 29 engaging internal axial grooves in the second housing element 2 making the nut element 27 ^{irrotational} ~~unrotatable~~, but axially displaceable in this housing element.

20 The grooves in the second housing element are each defined by pairs of spaced internal projections 30 in the second housing element. Together with the ribs 29 ending in a plate 41 at the end abutting the anti-rotary disc the projections 30 define a stop for the movement of the nut element as the plate 41 fits closely into the circular bore of the second housing element and consequently will abut the ends 25 of the projections 30 when the nut element is displaced into the second housing element. Thereby the maximal loading of the device is limited.

When the piston rod 22 is rotated relatively to the nut element 27 in one direction by rotating the first housing element relatively to the second housing element the nut element is moved away from its abutment 31 on the anti-rotary disc 30 23 and is displaced further into the second housing element compressing a helical spring 32 abutting at its one end the nut element and at its other end a protrusion

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on the inner surface of the tubular second housing element. The compressed spring 32 will try to press the nut element back to abut the disc 23, and this force exerted on the nut member will be transmitted to the piston rod and the piston through the threads in the nut element on the piston rod, thereby setting the content of the 5 cartridge under pressure. This pressure may be released by operating the valve to spray out the preselected dose of the medicine in the cartridge. During this spraying the piston is moved into the cartridge until the nut member abuts the disc 23 again.

At its end opposite the piston the piston rod is provided with a head 40 limiting the movement of the nut element along the piston rod to assure that a 10 dose exceeding the remaining liquid in the cartridge may not be preset.

The engagement between the piston rod 22 and the piston 21 is performed as a snap lock. This way the piston ²¹~~22~~ may be driven into the cartridge by the piston rod 22, the snap lock connection being flexible to permit the piston to follow marginal volume variations caused by temperature variations.

15 The loading of the device by turning the housing elements 1 and 2 in one direction relatively to each other may also be annulled by rotating the two housing elements in the opposite direction relatively to each other until the nut element is displaced to abut the disc again. The mutually abutting surfaces of the nut element and the disc 23 are provided with respective ramps to prevent further 20 relative rotation in this direction when the nut member abuts the disc. This way it is prevented that a further relative rotation of the housing elements in this direction will cause the piston rod to be drawn out of engagement with the piston.

The end of the tubular nut element opposite the disc is provided with a knob 33 having an outer cylindric surface fitting guidingly into the bore of the 25 tubular second housing element and an end surface flush with the end edge of the second housing element when the device is not loaded. When the device is loaded and the nut element is displaced away from the disc, the knob is protruding from the end of the second housing element giving a tactile and visible information of the status of the device, i.e. whether the device is loaded or not.

30 The spray nozzle element 13 is covered by a cap 34 when the device is not in use. This cap is provided with a clip 35, so that it can be carried in a pocket

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like a pencil. The cap 34 fits over the first housing element 1 and when fitted on is adjacent to and flush with the second housing element 2. The adjacent edges of the second housing element 2 and the cap 34 are provided with a projection 38 and a corresponding recess 39, respectively, the projection engaging the depression when the cap is fitted on.

The cap is provided with internal grooves 36 engaged by external ribs 37 on the first housing element 1. Thereby the cap can be used for rotating the first housing element 1 relatively to the second housing element 2 when the cap is appropriately axially displaced on the first housing element to bring the projection 38 out of engagement with the recess 39. The projection 39 is made as an arrow pointing on a scale on the cap, so that a dosing measured in units may be set by the turning of the two housing elements relatively to each other. The rotatable connection between the two housing elements is provided with a click mechanism providing a hearable and perceptible click at each two units set.

When the dose is set, the cap is removed from the device and the nozzle element is inserted in a nostril, and the release member 19 is pulled further over the first housing element to release the dose which is sprayed out through the nozzle at an angle of 0-30°. After use the cap is again fitted over the first housing element in a rotary position making the projection 38 engage the depression 39.

The first housing element forming the cartridge is made of a transparent material allowing the position of the piston to be observed to decide how much liquid is left. For this purpose the first housing element may be provided with a scale. When the cartridge is empty, the device may be disposed of.

Although the device is described with the cartridge forming an integral part of the first housing element, an embodiment wherein a separate cartridge is received in the first housing element will be within the scope of the invention. The device may also be a durable one in which only the cartridge and possibly the valve and the spray nozzle are changed when the cartridge is empty, whereas the dose setting mechanism is reused as a durable part.

The device is preferably used for dosing insulin which may be assimilated through the nasal mucous membranes, but it may also be used for the

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administration of other kinds of medicine which should be added as a spray in
preset doses, e.g. for curing eczema.

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 We CLAIM\$:

1. A device for nasal administration of a number of measured doses of a liquid medicine, especially insulin, comprising a first and a second housing element coupled together to allow rotation but no axial displacement of the first housing element (1) with respect to the second housing element (2), said first housing element (1) comprising a cartridge containing the liquid and being sealed by a piston (21) at the end coupled to the second housing element (2) and being at its other end closed by a valve (7,9) to communicate the liquid in the cartridge with a spray nozzle (12) when opened, characterized in that the device further comprises a threaded piston rod (22) engaging the piston (21) of the cartridge unrotatably with respect to the first housing element (1) and disposed in the second housing element (2) to move axially therein, a nut element (27) mounted unrotatably but axially displaceably in the second housing element (2) and engaging the thread of the piston rod (22), a helical spring (32) abutting at its one end an internal annular abutment on the second housing element (2) and at its other end a shoulder on the nut element (27) to press this nut element and thereby the piston rod (22) and the piston (21) in the directions towards the outlet end of the cartridge setting the liquid therein under pressure to be released by opening the valve (7,9) for spraying out a dose of the liquid, the housing elements (1,2), the rod (22), and the nut element (27) cooperating so that relative rotation between the housing elements (1,2) in a selected direction causes relative rotation between the rod (22) and the nut element making the nut element move axially in the second housing element (2) in a direction to compress the helical spring (32).

2. A device according to claim 1, characterized in that the piston rod (22) is snap locked into the piston (21).

b
 3. A device according to claim 1 or 2, characterized in that the nozzle (12) sprays out the liquid at an angle of 0-30°

b
 4. A device according to ^{claim 1} any of the preceding claims, characterized in that the nut element (27) defines at least one radially protruding, axially extending projection (29) on an exterior portion thereof; and the projection is received in an axially extending groove in an inner portion of the second housing element (2).

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B

5. A device according to ^{claim 1}any of the preceding claims, characterized in that a stop (30,41) is provided limiting axial movement of the nut element (27) into the second housing element (2).

b

6. A device according to ^{claim 1}any of the preceding claims, characterized in 5 that a stop (40) is provided limiting the movement of the nut element (27) along the piston rod (22).

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ins
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7. A device according to ^{claim 1}any of the preceding claims, ^{further}characterized in that it has a removable protective cap (34) configured to receive the first housing element (1) and ~~abutting when mounted there on~~ the second housing element (2); 10 and means (36,37) for releasably coupling the protective cap (34) and the first housing element (1) for rotation together, so that rotation of the protective cap (34) with respect to the second housing element (2) causes rotation of the first housing element (1) with respect to the second housing element (2).

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8. A device according to claim 7, characterized in that the abutting 15 edges of the second housing element (2) and the protective cap (34) comprise pointing means and scale means, respectively, ^{for measuring}to measure the relative rotation of the protective cap (34) with respect to the second housing element (2).

9. A device according to claim 8, characterized in that means are provided for providing detents at selected rotational positions of the first housing 20 element (1) with respect to the second housing element (2).

10. A device according to claim 9, characterized in that the coupling means (36,37) allow the protective cap (34) to receive the first housing element (1) in multiple different angular positions of the protective cap (34) with respect to the first housing element (1) to allow the protective cap (34) to be oriented at a selected 25 position with respect to the second housing element (2), regardless of the detent rotational position of the first housing element (1) in the second housing element (2).

C

11. A device according to claim 9, characterized in that the abutting ^{of the protective cap and the second housing element}edges have interlocking means (38,39) for defining a selected angular position of the protective cap (34) with respect to the second housing element (2).

C

30 12. A device according to claim 10, characterized in that the interlocking means comprise a recess (38) on the abutting ^{edges}edge of the protective cap ^A

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C (34) and a projection (39) on the abutting ^{edges} of the second housing element (2), the projection (39) being shaped to fit into the recess (38) to define the selected position.

B 13. A device according to ^{claim 1} ~~any of the preceding claims~~, characterized in that the piston rod (22) is made ^{irrotational} ~~irrotatable~~ with respect to the first housing element (1) by fitting through an opening in an anti-rotation disc (23), the opening being mainly circular with at least one projection (26) protruding into the opening, by the piston rod (22) having a corresponding profile with recesses (25) corresponding to the projections (26), and by the anti-rotation disc (23) being at its periphery provided with alternating spaces and teeth (42) fitting into a castellated end of the first housing element (1).

C 14. A device according to claim 13, characterized in that the anti-rotation disc (23) serves as an abutment for the nut element (27) ^{and limits} ~~limiting its~~ movement ^{of the nut element} towards the cartridge.

C 15. A device according to claim ¹⁴ ~~13~~, characterized in that the ^{abutment between} ~~abutting~~ faces of the nut element (27) and the anti-rotation disc (23) are formed as annular ramps (31) which when in mutual abutment allow only relative rotation of the first and second housing element in a device loading direction.

B 16. A device according to claims ¹⁵ ~~14~~, characterized in that the nut element (27) has an tubular extension coaxially surrounding the piston rod (22) ^{and} ~~and~~ terminated by a knob (33) ^{on} ~~at the~~ outer end of the second housing element (2), ^{the} ~~this~~ knob (33) being flush with the edge of ^{the} ~~this~~ outer end ^{of the second housing element} when the annular ramps of the ^{anti-rotation} ~~anti-rotation~~ disc and the nut ^{element} ~~member~~ are in mutual abutment.

Ln B² >

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ABSTRACT

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A pen shaped device for nasal administration of doses of a liquid medicine, comprising a first and a second housing element, the first housing element (1) comprising a cartridge for the medicine, this cartridge being at one end closed by a piston (21) and being at its other end closed by a valve (7,9), which may be opened to connect the cartridge to a spray nozzle (12). When the two housing elements are rotated relatively to each other, a nut member (27) is proportional to the rotation moved along a threaded piston rod (22) to compress a helical spring (32) to act via the nut element (27) and the piston rod (22) on the piston (21) to put the content of the cartridge under pressure, which pressure may be released by opening the valve (7,9) to lead the medicine in the cartridge to the nozzle (12).

13

COMBINED DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY
(Includes Reference to PCT International Applications)

793,413
* Supl Decl (paper #)
b
6
Docket Number:

3573.204-WO

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

NOSE PEN

the specification of which (check only one item below):

☐ is attached hereto

☐ was filed as United States application

Serial No. _____

on _____,

and was amended

on _____ (if applicable).

☒ was filed as PCT international application

Number PCT/DK91/00400

on December 19, 1991

and was amended under PCT Article 19

on _____ (if applicable).

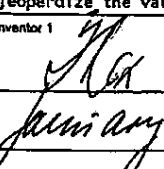
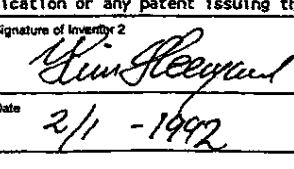
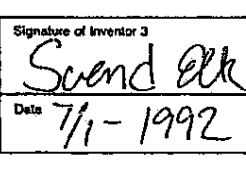
I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign applications(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign applications(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed:

PRIOR FOREIGN/PCT APPLICATION(S) AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. 119:

COUNTRY	APPLICATION NUMBER	DATE OF FILING	PRIORITY CLAIMED
Denmark	3028/90	December 21, 1990	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO

COMBINED DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY (includes Reference to PCT International applications)		Attorney's Docket Number: 73.204-US	
I hereby claim the benefit under Title 35, United States Code §120 of any United States application(s) or PCT international application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this applications is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application(s) and the national or PCT international filing date of this application:			
PRIOR U.S. APPLICATIONS OR PCT INTERNATIONAL APPLICATIONS DESIGNATING THE U.S. FOR BENEFIT UNDER 35 U.S.C. 120:			
U.S. APPLICATIONS		STATUS (Check one)	
U.S. APPLICATION NUMBER	U.S. FILING DATE	Patented	Pending
PCT APPLICATIONS DESIGNATING THE U.S.			
APPLICATION NO.	FILING DATE	US SERIAL NUMBERS ASSIGNED (if any)	
PCT/DK91/00400	December 19, 1991		X
POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.			
Steve T. Zelson, Esq. Elias J. Lambiris, Esq. Reg. No. 30,335 Reg. No. 33,728			
Send Correspondence to: <u>Steve T. Zelson, Esq.</u> <u>Novo Nordisk of North America, Inc.</u> <u>405 Lexington Avenue, Suite 6200</u> <u>New York, New York 10017</u>			Direct Telephone Calls To: Steve T. Zelson (212) 867-0123
1	Full Name of Inventor <u>REX</u>	Family Name <u>REX</u>	First Given Name <u>Jørn</u>
	Residence & Citizenship <u>Roskilde</u>	City <u>Roskilde</u>	State or Foreign Country <u>Denmark DKX</u>
	Post Office Address <u>Hyldeboften 6, Gundsoemøgle</u>	City <u>DK-4000 Roskilde</u>	State & Zip Code/Country <u>Denmark</u>
2	Full Name of Inventor <u>STEENGAARD</u>	Family Name <u>STEENGAARD</u>	First Given Name <u>Kim</u>
	Residence & Citizenship <u>Hvidovre</u>	City <u>Hvidovre</u>	State or Foreign Country <u>Denmark DKX</u>
	Post Office Address <u>Ketilstorp Allé 53</u>	City <u>DK-2650 Hvidovre</u>	State & Zip Code/Country <u>Denmark</u>
3	Full Name of Inventor <u>ELK</u>	Family Name <u>ELK</u>	First Given Name <u>Svend</u>
	Residence & Citizenship <u>Birkeroed</u>	City <u>Birkeroed</u>	State or Foreign Country <u>Denmark DKX</u>
	Post Office Address <u>Lynghorshave 48</u>	City <u>DK-3460 Birkeroed</u>	State & Zip Code/Country <u>Denmark</u>
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.			
Signature of Inventor 1 	Signature of Inventor 2 	Signature of Inventor 3 	
Date <u>2 January</u>	Date <u>2/1 - 1992</u>	Date <u>7/1 - 1992</u>	

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As Originally Filed
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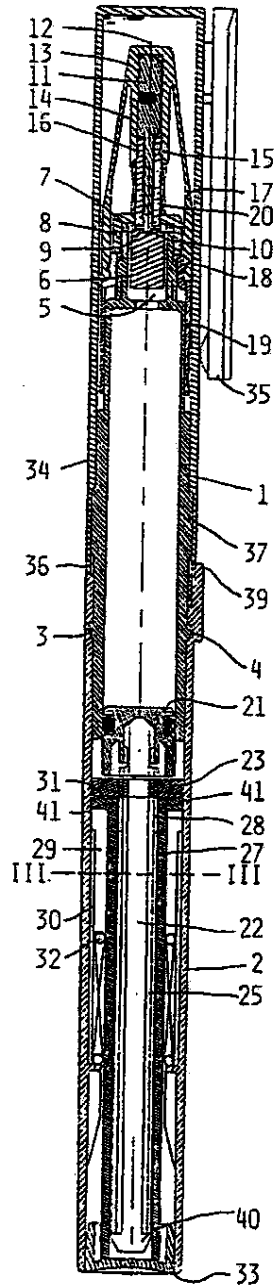


Fig. 1

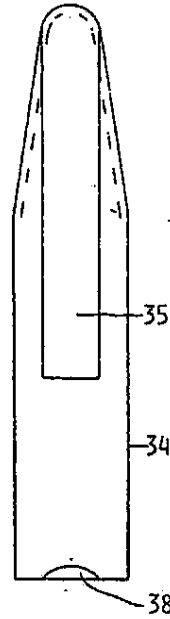


Fig. 2

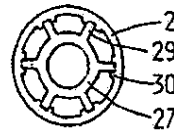


Fig. 3

REPLACEMENT SHEET

PRINT OF DRAWINGS
As Originally Filed
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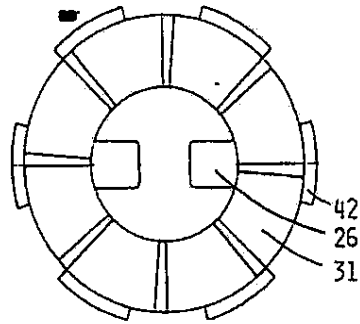


Fig. 4

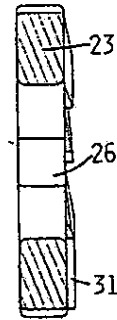


Fig. 5

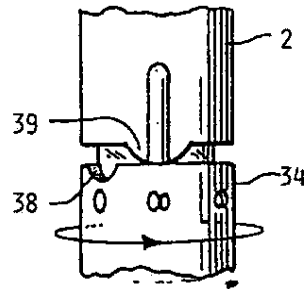


Fig. 6

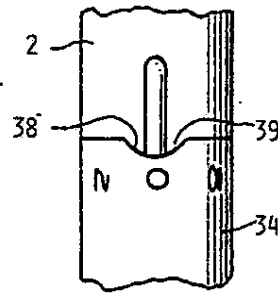


Fig. 7

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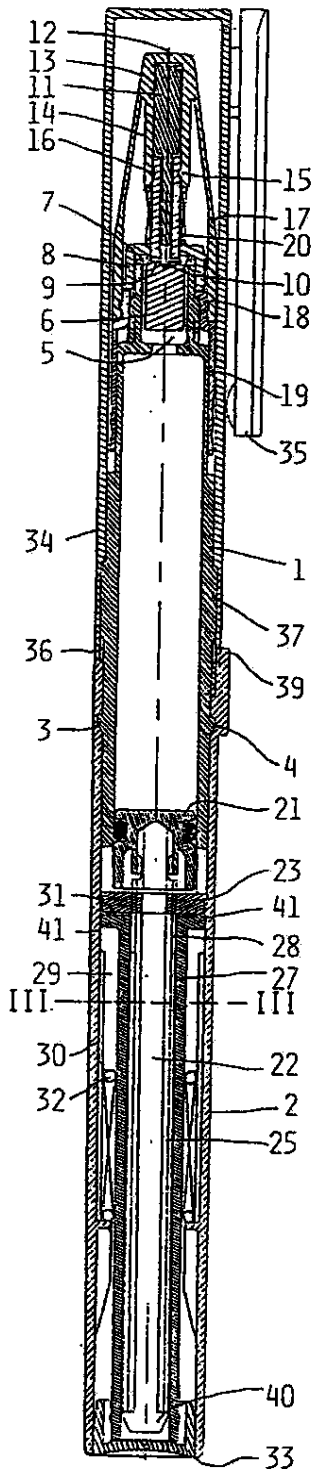


Fig. 1

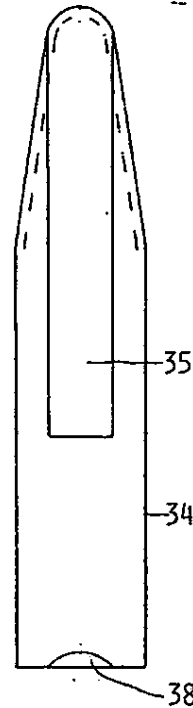


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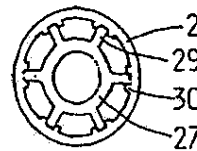


Fig. 3

REPLACEMENT SHEET

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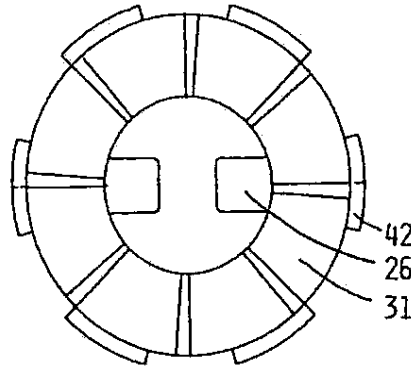


Fig. 4

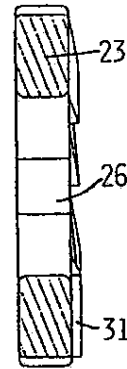


Fig. 5

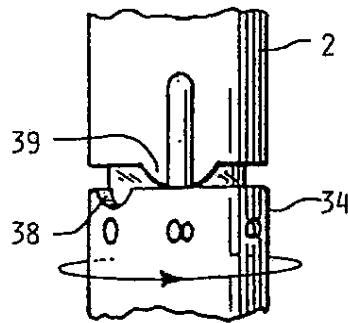


Fig. 6

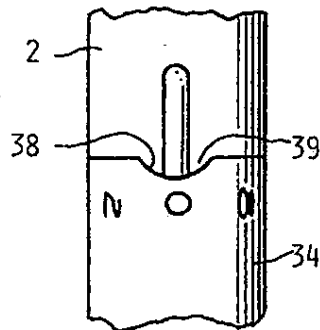


Fig. 7

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08 Rec'd PCT/PTO 1 3 JAN 1992

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FORM PTO-1200 (REV. 3-90)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTORNEY'S DOCKET NUMBER 3573.204-US	
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)					
INTERNATIONAL APPLICATION NO. PCT/DK91/00400		INTERNATIONAL FILING DATE December 19, 1991		PRIORITY DATE CLAIMED December 21, 1990	
TITLE OF INVENTION NOS. PEN					
APPLICANT(S) FOR DO/EO/US Jørn Rex; Kim Steengaard & Svend Elk					
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following under 35 U.S.C. 371: 1. <input checked="" type="checkbox"/> This express request to immediately begin national examination procedures (35 U.S.C. 371(f)). 2. <input checked="" type="checkbox"/> The U.S. National Fee (35 U.S.C. 371(c)(1)) and other fees as follows:					
CLAIMS	(1) FOR	(2) NUMBER FILED	(3) NUMBER EXTRA	(4) RATE	(5) CALCULATION
	TOTAL CLAIMS	17 -20=	0	x\$20.00	\$ 0.00
	INDEPENDENT CLAIMS	1 -3=	0	x\$72.00	\$ 0.00
	MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$220.00	\$ 220.00
	BASIC NATIONAL FEE (37 CFR 1.492(a)(1)-(4)): <input type="checkbox"/> International preliminary examination fee paid to USPTO (37 CFR 1.482)\$620 <input type="checkbox"/> No international preliminary examination fee paid to USPTO (37 CFR 1.482) but international search fee paid to USPTO (37 CFR 1.445(a)(2))\$690 <input checked="" type="checkbox"/> Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO\$920 <input type="checkbox"/> International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(2) to (4)\$ 50				\$ 920.00
	Surcharge of \$130.00 for furnishing the National fee or oath or declaration later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 mos. from the earliest claimed priority date (37 CFR 1.492(e)).				\$ 0.00
	TOTAL OF ABOVE CALCULATIONS				= \$1,140.00
	Reduction by 1/2 for filing by small entity, if applicable. Affidavit must be filed also. (Note 37 CFR 1.9, 1.27, 1.28.)				
	SUBTOTAL				+
	Processing fee of \$30. for furnishing the English Translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 mos. from the earliest claimed priority date (37 CFR 1.492(f)).				
	TOTAL NATIONAL FEE				\$1,140.00
	Fee for recording the enclosed assignment (37 CFR 1.21(h)).				+
	TOTAL FEES CHARGED				\$1,140.00
a. <input type="checkbox"/> A check in the amount of \$_____ to cover the above fees is enclosed. b. <input checked="" type="checkbox"/> Please charge my Deposit Account No. 14-1447 in the amount of \$1,140.00 to cover the above fees. A duplicate copy of this sheet is enclosed. c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-1447. A duplicate of this sheet is enclosed.					

SAN00941625

ATTORNEY'S DOCKET NUMBER
3573.204-US

3. A copy of the International Application as filed (35 U.S.C. 371(c)(2)).
- ☐ is transmitted herewith (required only if not transmitted by the International Bureau).
 - ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
 - ☒ has been transmitted by the International Bureau.
4. ☐ A translation of the International Application into English (35 U.S.C. 371(c)(2)).
5. Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)).
- ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
 - ☐ have been transmitted by the International Bureau.
6. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
7. ☒ An oath or declaration of the inventor (35 U.S.C. 371(c)(4)).
8. ☐ A translation of the Annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).
- Other document(s) or information included:
- ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
 - ☐ An assignment document for recording.
Please mail the recorded assignment document to:
 - ☐ the person whose signature, name & address appears at the bottom of this page.
 - ☐ the following:
11. The above checked items are being transmitted
- ☒ before the 18th month publication.
 - ☐ after publication and the Article 20 communication but before 20 months from the priority date.
 - ☐ after 20 months but before 22 months (surcharge and/or processing fee included).
 - ☐ after 22 months (surcharge and/or processing fee included).
Note: Petition to revive (37 CFR 1.137(a) or (b)) is necessary if 35 U.S.C. 371 requirements submitted after 22 months and no proper demand for International Preliminary Examination was made by 19 months from the earliest claimed priority date.
 - ☐ by 30 months and a proper demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
 - ☐ after 30 months but before 32 months and a proper demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date (surcharge and/or processing fee included).
 - ☐ after 32 months (surcharge and/or processing fee included).
Note: Petition to revive (37 CFR 1.137(a) or (b)) is necessary if 35 U.S.C. 371 requirements submitted after 32 months and a proper demand for International Preliminary Examination was made by 19 months from the earliest claimed priority date.
12. At the time of transmittal, the time limit for amending claims under Article 19
- ☐ has expired and no amendments were made.
 - ☐ has not yet expired.
13. ☐ Certain requirements under 35 U.S.C. 371 were previously submitted by the applicant on _____ date
namely:

Elias J. Lambiris
NAME

Novo Nordisk of North America, Inc.

405 Lexington Avenue, Suite 6200
ADDRESS

New York, New York 10017

(212) 867-0123
TELEPHONE

Elias J. Lambiris
SIGNATURE

33,728
REGISTRATION NUMBER

International Application Number: 7 DK91/00400

Fees SUBMITTED OR AUTHORIZED:

NOTE: Please stamp
file "FILED"
UNDER 35 USC 371Non-Small Entity Patent Processing Fees**11/793412**

FEE	CODE	CASH	CHARGE
Basic			
\$620	956	\$.00	\$.00
\$690	958	\$.00	\$.00
\$920	960	\$.00	\$ <u>920</u> .00
\$ 90	962	\$.00	\$ 920 .00
Each Independent Claim in <u>EXCESS</u> OF 3	964	\$.00	\$.00
Claim(s) in <u>EXCESS</u> OF 20	966	\$.00	\$.00
Multiple Dependent Claim(s)	968	\$.00	\$ <u>220</u> .00
Surcharge for Late Fee/Oath or Declaration	154	\$.00	\$.00

I. Small Entity Patent Processing Fees

FEE	CODE	CASH	CHARGE
Basic			
\$310	957	\$.00	\$.00
\$345	959	\$.00	\$.00
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Each Independent Claim in <u>EXCESS</u> OF 3	965	\$.00	\$.00
Claim(s) in <u>EXCESS</u> OF 20	967	\$.00	\$.00
Multiple Dependent Claim(s)	969	\$.00	\$.00
Surcharge for Late Fee/Oath or Declaration	254	\$.00	\$.00

I. Other Fees - NO SMALL ENTITY REDUCTION

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Surcharge for Late Trans.	156	\$.00	\$.00
Assignment	581	\$.00	\$.00
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\$.00
TOTAL CASH\$1140 .00
TOTAL CHARGE

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08 Rec'd PCT/US 1 3 JAN 1992

11/793412

Attorney Docket No. 3573.204-US

PATENT

IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

INTERNATIONAL APPLICATION NO.: PCT/DK91/00400

INTERNATIONAL FILING DATE: December 19, 1991

PRIORITY DATE: December 21, 1990

TITLE: NOSE PEN

APPLICANT(S) FOR DO/EO/US: Rex et al.

EXPRESS MAIL CERTIFICATE

Box PCT
Hon. Commissioner of Patents and Trademarks
Washington, DC 20231

Sir:

Express Mail Label No. RB813924947US

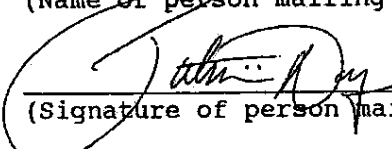
Date of Deposit January 13, 1992

I hereby certify that the following attached papers
or fee

1. Transmittal Letter to the DO/EO/US
(in duplicate)
2. Executed Combined Declaration and Power of
Attorney

are being deposited with the United States Postal Service
"Express Mail Post Office to Addressee" under 37 C.F.R. 1.10
on the date indicated above and is addressed to the
Commissioner of Patents and Trademarks, Washington, DC 20231.

Patricia Dugue
(Name of person mailing paper(s) or fee)


(Signature of person mailing paper(s) or fee)


Mailing Address:

Novo Nordisk of North America, Inc.
405 Lexington Avenue, Suite 6200
New York, NY 10017

SAN00941628

RECORD COPY
INTERNATIONAL APPLICATION
UNDER THE
PATENT COOPERATION TREATY
REQUEST

THE UNDERSIGNED REQUESTS THAT THE PRESENT
 INTERNATIONAL APPLICATION BE PROCESSED
 ACCORDING TO THE PATENT COOPERATION TREATY

(The following is to be filled in by the receiving Office)	
INTERNATIONAL APPLICATION No.:	PCT/DK 91/00400
INTERNATIONAL FILING DATE:	19 DECEMBER 1991
 Danish Patent Office PCT International Application Name of receiving Office and "PCT International Application"	
Applicant's or agent's file reference (indicated by applicant if desired)	3573.204-W0, EIT

Box No. I TITLE OF INVENTION	22 Rec'd PCT/PTO 16 JUL 1992
[NOSE PEN] ^A	
Box No. II APPLICANT (WHETHER OR NOT ALSO INVENTOR); DESIGNATED STATES FOR WHICH HE/SHE/IT IS APPLICANT. Use this box for indicating the applicant or, if there are several applicants, one of them. If more than one person (includes, where applicable, a legal entity) is involved, continue in Box No. III. The person identified in this box is (mark one check-box only): <input type="checkbox"/> applicant and inventor* <input checked="" type="checkbox"/> applicant only Name and address:** NOVO NORDISK A/S Novo Allé DK-2880 Bagsvaerd Denmark	
Telephone number (including area code): 44 44 88 88	Telegraphic address: telanovo
Teleprinter address: 37173	
State of nationality: DK State of residence:* DK The person identified in this box is <i>applicant</i> for the purposes of (mark one check-box only): <input type="checkbox"/> all designated States <input checked="" type="checkbox"/> all designated States except the United States of America <input type="checkbox"/> the United States of America only <input type="checkbox"/> the States indicated in the "Supplemental Box"	
Box No. III FURTHER APPLICANTS, IF ANY; (FURTHER) INVENTORS, IF ANY; DESIGNATED STATES FOR WHICH THEY ARE APPLICANTS (IF APPLICABLE). A separate sub-box has to be filled in in respect of each person (includes, where applicable, a legal entity). If the following two sub-boxes are insufficient, continue in the "Supplemental Box," (giving there for each additional person the same indications as those requested in the following two sub-boxes) or by using a "continuation sheet." The person identified in this sub-box is (mark one check-box only): <input checked="" type="checkbox"/> applicant and inventor* <input type="checkbox"/> applicant only <input type="checkbox"/> inventor only Name and address:** REX, Jørn Hyldeoften 6 Gundsømagle DK-4000 Roskilde Denmark If the person identified in this sub-box is <i>applicant</i> (or <i>applicant and inventor</i>), indicate also: State of nationality: DK State of residence:* DK and whether that person is <i>applicant</i> for the purposes of (mark one check-box only): <input type="checkbox"/> all designated States <input type="checkbox"/> all designated States except the United States of America <input checked="" type="checkbox"/> the United States of America only <input type="checkbox"/> the States indicated in the "Supplemental Box"	
The person identified in this sub-box is (mark one check-box only): <input checked="" type="checkbox"/> applicant and inventor* <input type="checkbox"/> applicant only <input type="checkbox"/> inventor only Name and address:** STEENGAARD, Kim Ketilstorp Allé 53 DK-2650 Hvidovre Denmark If the person identified in this sub-box is <i>applicant</i> (or <i>applicant and inventor</i>), indicate also: State of nationality: DK State of residence:* DK and whether that person is <i>applicant</i> for the purposes of (mark one check-box only): <input type="checkbox"/> all designated States <input type="checkbox"/> all designated States except the United States of America <input checked="" type="checkbox"/> the United States of America only <input type="checkbox"/> the States indicated in the "Supplemental Box"	
* If the person indicated as "applicant and inventor" or as "inventor only" is not an <i>inventor</i> for the purposes of all the designated States, give the necessary indications in the "Supplemental Box." ** Indicate the name of a natural person by giving his/her family name first followed by the given name(s). Indicate the name of a legal entity by its full official designation. In the address, include both the postal code (if any) and the State (name). *** If residence is not indicated, it will be assumed that the State of residence is the same as the State indicated in the address.	

Sheet number 2

PCT/RO 91/00400

Box No. III CONTINUATION (IF REQUIRED) FURTHER APPLICANTS, IF ANY; (FURTHER) INVENTORS, IF ANY; DESIGNATED STATES FOR WHICH THEY ARE APPLICANTS (IF APPLICABLE). A separate sub-box has to be filled in in respect of each person (includes, where applicable, a legal entity).

The person identified in this sub-box is (mark one check-box only): ☒ applicant and inventor* ☐ applicant only ☐ inventor only*
Name and address:**

ELK, Svend
Lyngborghave 48
DK-3460 Birkerød
Denmark

If the person identified in this sub-box is *applicant* (or *applicant and inventor*), indicate also:

State of nationality: DK State of residence:*** DK
and whether that person is *applicant* for the purposes of (mark one check-box only):
☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the "Supplemental Box"

The person identified in this sub-box is (mark one check-box only): ☐ applicant and inventor* ☐ applicant only ☐ inventor only*
Name and address:**

If the person identified in this sub-box is *applicant* (or *applicant and inventor*), indicate also:

State of nationality: State of residence:***
and whether that person is *applicant* for the purposes of (mark one check-box only):
☐ all designated States ☐ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the "Supplemental Box"

The person identified in this sub-box is (mark one check-box only): ☐ applicant and inventor* ☐ applicant only ☐ inventor only*
Name and address:**

If the person identified in this sub-box is *applicant* (or *applicant and inventor*), indicate also:

State of nationality: State of residence:***
and whether that person is *applicant* for the purposes of (mark one check-box only):
☐ all designated States ☐ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the "Supplemental Box"

The person identified in this sub-box is (mark one check-box only): ☐ applicant and inventor* ☐ applicant only ☐ inventor only*
Name and address:**

If the person identified in this sub-box is *applicant* (or *applicant and inventor*), indicate also:

State of nationality: State of residence:***
and whether that person is *applicant* for the purposes of (mark one check-box only):
☐ all designated States ☐ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the "Supplemental Box"

* If the person indicated as "applicant and inventor" or as "inventor only" is not an *inventor* for the purposes of all the designated States, give the necessary indications in the "Supplemental box."

** Indicate the name of a natural person by giving his/her family name first followed by the given name(s). Indicate the name of a legal entity by its full official designation. In the address, include both the postal code (if any) and the State (name).

*** If residence is not indicated, it will be assumed that the State of residence is the same as the State indicated in the address.

If this continuation sheet is not used, it need not be included in the Request.

PCT/OK 91/00400

Sheet number 3

Box No. IV AGENT (IF ANY) OR COMMON REPRESENTATIVE (IF ANY); ADDRESS FOR NOTIFICATIONS (IN CERTAIN CASES). A common representative may be appointed only if there are several applicants and if no agent is or has been appointed; the common representative must be one of the applicants.
The following person (includes, where applicable, a legal entity) is hereby/has been appointed as agent or common representative to act on behalf of the applicant(s) before the competent International Authorities:

Name and address, including postal code and country:

If the space below is used instead for an address for notifications, mark here: ☐

NOVO NORDISK A/S
Novo Allé
DK-2880 Bagsvaerd
Denmark
Att.: Patent Department

Telephone number (including area code):
44 44 88 88

Telegraphic address:
telanovo

Teleprinter address:
37304

Box No. V DESIGNATION OF GROUPS OF STATES OR STATES⁽¹⁾; CHOICE OF CERTAIN KINDS OF PROTECTION OR TREATMENT. The following designations are hereby made (please mark the applicable check-boxes):

Regional Patent

- ☒ **EP** European Patent⁽²⁾: AT Austria, BE Belgium, CH and LI Switzerland and Liechtenstein, DE Germany, DK Denmark, ES Spain, FR France, GB United Kingdom, GR Greece, IT Italy, LU Luxembourg, NL Netherlands, SE Sweden, and any other State which is a Contracting State of the European Patent Convention and of the PCT
- ☒ **OA** OAPI Patent: Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Congo, Gabon, Mali, Mauritania, Senegal, Togo, and any other State which is a Contracting State of OAPI and of the PCT; if other OAPI title desired, specify on dotted line⁽³⁾:

National Patent (if other kind of protection or treatment desired, specify on dotted line⁽³⁾)

- | | |
|---|---|
| <input type="checkbox"/> AT Austria ⁽³⁾ | <input checked="" type="checkbox"/> KR Republic of Korea ⁽³⁾ |
| <input checked="" type="checkbox"/> AU Australia ⁽³⁾ | <input checked="" type="checkbox"/> LK Sri Lanka |
| <input checked="" type="checkbox"/> BB Barbados | <input type="checkbox"/> LU Luxembourg ⁽³⁾ |
| <input checked="" type="checkbox"/> BG Bulgaria ⁽³⁾ | <input checked="" type="checkbox"/> MC Monaco ⁽³⁾ |
| <input checked="" type="checkbox"/> BR Brazil ⁽³⁾ | <input checked="" type="checkbox"/> MG Madagascar |
| <input checked="" type="checkbox"/> CA Canada | <input checked="" type="checkbox"/> MW Malawi ⁽³⁾ |
| <input type="checkbox"/> CH and LI Switzerland and Liechtenstein | <input type="checkbox"/> NL Netherlands |
| <input type="checkbox"/> DE Germany ⁽³⁾ | <input checked="" type="checkbox"/> NO Norway |
| <input type="checkbox"/> DK Denmark | <input checked="" type="checkbox"/> PL Poland ⁽³⁾ |
| <input type="checkbox"/> ES Spain ⁽³⁾ | <input checked="" type="checkbox"/> RO Romania |
| <input checked="" type="checkbox"/> FI Finland | <input checked="" type="checkbox"/> SD Sudan |
| <input type="checkbox"/> GB United Kingdom | <input type="checkbox"/> SE Sweden |
| <input checked="" type="checkbox"/> HU Hungary | <input checked="" type="checkbox"/> SU Soviet Union ⁽³⁾ |
| <input checked="" type="checkbox"/> JP Japan ⁽³⁾ | <input type="checkbox"/> US United States of America ⁽³⁾ |
| <input checked="" type="checkbox"/> KP Democratic People's Republic of Korea ⁽³⁾ | |

Space reserved for designating States (for the purposes of a national patent) which have become party to the PCT after the issuance of this sheet:

CS Czechoslovakia

(1) The applicant's choice of the order of designations may be indicated by marking the check-boxes with sequential arabic numerals (see also the "Notes to Box No. V").

(2) The selection of particular States for a European patent can be made upon entering the national (regional) phase before the European Patent Office (see also the "Notes to Box No. V").

(3) If another kind of protection or a title of addition or, in the United States of America, treatment as a continuation or a continuation-in-part is desired, specify according to the instructions given in the "Notes to Box No. V."

Sheet number 4

PCT/DK 91/00400

Box No. VI PRIORITY CLAIM (IF ANY). The priority of the following earlier application(s) is hereby claimed:			
Country (country in which it was filed if national application; one of the countries for which it was filed if regional or international application)	Filing Date (day, month, year)	Application No.	Office of filing (fill in only if the earlier application is an international application or a regional application)
(1) DK	21 December 1990 (21.12.90)	3028/90	
(2)			
(3)			
(Letter codes may be used to indicate country and/or Office of filing)			
When the earlier application was filed with the Office which, for the purposes of the present international application, is the receiving Office, the applicant may, <i>against payment of the required fee</i> , ask the following:			
<input checked="" type="checkbox"/> the receiving Office is hereby requested to prepare and transmit to the International Bureau a certified copy of the above-mentioned earlier application/of the earlier applications identified above by the numbers (insert the applicable numbers)			
Box No. VII EARLIER SEARCH (IF ANY). Fill in where a search (international, international-type or other) by the International Searching Authority has already been requested (or completed) and the said Authority is now requested to base the international search, to the extent possible, on the results of the said earlier search. Identify such search or request either by reference to the relevant application (or the translation thereof) or by reference to the search request.			
International application number or number and country (or regional Office) of other application:		International/regional/national filing date:	
Date of request for search:		Number (if available) given to search request:	
Box No. VIII SIGNATURE OF APPLICANT(S) OR AGENT			
Jørn Rex <i>JR</i>		E. Trønner Hansen; Patent Counsel NOVO NORDISK A/S <i>Svend Elk</i> Svend Elk	
Kim Steengaard 29/11-91 <i>Kim Steengaard</i>			
If the present Request form is signed on behalf of any applicant by an agent, a separate power of attorney appointing the agent and signed by the applicant is required. If in such case it is desired to make use of a general power of attorney (deposited with the receiving Office), a copy thereof must be attached to this form.			
Box No. IX CHECK LIST (To be filled in by the Applicant)		This international application as filed is accompanied by the items marked below:	
This international application contains the following number of sheets:		1. <input type="checkbox"/> separate signed power of attorney	
1. request	4 sheets	2. <input type="checkbox"/> copy of general power of attorney	
2. description	10 sheets	3. <input type="checkbox"/> priority document(s) (see Box No. VI)	
3. claims	3 sheets	4. <input type="checkbox"/> receipt of the fees paid or revenue stamps	
4. abstract	1 sheet	5. <input checked="" type="checkbox"/> cheque for the payment of fees	
5. drawings	2 sheets	6. <input type="checkbox"/> request to charge deposit account	
Total	20 sheets	7. <input checked="" type="checkbox"/> other document (specify) Copy of Office Action in DK 3028/90 of 26 September 1991	
Figure number <u>1</u> of the drawings (if any) is suggested to accompany the abstract for publication.			
(The following is to be filled in by the receiving Office)			
1. Date of actual receipt of the purported international application:		RO/DK 19 DECEMBER 1991 (19.12.91)	
2. Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application:			
3. Date of timely receipt of the required corrections under Article 11 of the PCT:			
4. Drawings <input type="checkbox"/> Received <input type="checkbox"/> No Drawings			
(The following is to be filled in by the International Bureau)			
Date of receipt of the record copy:		22 JANUARY 1992 (22.01.92)	

Form PCT/RO/101 (last sheet) (January 1991)

See notes on accompanying sheet

SAN00941632

INTERNATIONAL SEARCH REPORT

International Application No PCT/DK 91/00400

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ⁶		
According to International Patent Classification (IPC) or to both National Classification and IPC		
IPC5: A 61 M 11/06		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁷		
Classification System	Classification Symbols	
IPC5	A 61 M; B 05 B; B 05 C	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in Fields Searched ⁸		
SE,DK,FI,NO classes as above		
III. DOCUMENTS CONSIDERED TO BE RELEVANT⁹		
Category ¹⁰	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
A	GB, A, 1379688 (CIBA-GEIGY AG) 8 January 1975, see the whole document --	1
A	EP, A1, 0308100 (BESPAK PLC) 22 March 1989, see the whole document --	1
A	WO, A3, 9115303 (BESPAK PLC) 17 October 1991, see the whole document --	1
A	US, A, 4962868 (BORCHARD) 16 October 1990, see the whole document -- -----	1
<p>¹⁰ Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance, the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance, the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&" document member of the same patent family</p>		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
21st February 1992	1992 -03- 0 2	
International Searching Authority	Signature of Authorized Officer	
SWEDISH PATENT OFFICE	Lena Johansson	

Form PCT/ISA/210 (second sheet) (January 1985)

SAN00941633

**ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO. PCT/DK 91/00400**

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the Swedish Patent Office EDP file on 30/12/91. The Swedish Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
GB-A- 1379688	75-01-08	AT-B- 321190	75-03-25
		AT-B- 321191	75-03-25
		AU-B- 467599	75-12-04
		AU-B- 470526	76-03-18
		AU-D- 4157472	73-12-20
		AU-D- 4157572	73-12-20
		BE-A- 782785	72-10-30
		BE-A- 782786	72-10-30
		CA-A- 982092	76-01-20
		CA-A- 982093	76-01-20
		CH-A- 602433	78-07-31
		DE-A-B-C 2220252	73-01-04
		DE-A-B- 2220253	72-11-16
		FR-A-B- 2137512	72-12-29
		FR-A- 2186853	74-01-11
		GB-A- 1385056	75-02-26
		LU-A- 65262	73-10-30
		LU-A- 65264	73-10-30
		NL-A- 7205838	72-11-01
		NL-A- 7205839	72-11-01
		SE-B-C- 394952	77-07-25
		SE-B-C- 394953	77-07-25
		US-A- 3733010	73-05-15
EP-A1- 0308100	89-03-22	AU-D- 2188888	89-03-09
		GB-A- 2209564	89-05-17
		GB-A- 2240816	91-08-14
		US-A- 4896832	90-01-30
WO-A3- 9115303	91-10-17	NONE	
US-A- 4962868	90-10-16	DE-A-C- 3810262	89-10-12
		EP-A- 0334349	89-09-27
		JP-A- 2011158	90-01-16

JUL 1992

PATENT COOPERATION TREATY

	INTERNATIONAL APPLICATION NO. PCT/DK91/00400
NOTIFICATION TO THE DESIGNATED OFFICE OF RECEIPT OF RECORD COPY issued under PCT Rule 24.2(a)	To: United States Patent and Trademark Office Washington, D.C.
APPLICANT'S OR AGENT'S FILE REFERENCE: 3573.204-WO, EIT	In its capacity as a designated Office
DATE OF MAILING OF THIS NOTIFICATION: 22 January 1992 (22.01.92)	From: The International Bureau of WIPO 1211 Geneva 20 Switzerland
NAME(S) OF APPLICANT(S): REX, Jørn et al.	
INTERNATIONAL FILING DATE: 19 December 1991 (19.12.91)	
PRIORITY DATE(S) CLAIMED: 21 December 1990 (21.12.90)	
DATE OF RECEIPT OF RECORD COPY BY INTERNATIONAL BUREAU: 22 January 1992 (22.01.92)	
J.D. Hawkins (Authorized Officer)	

Form PCT/IB/302 (January 1984)

SAN00941636

REC'D PCT/PTO

FEB 11 1992

SAN00941637

No. 17/1992

PCT GAZETTE - SECTION I

7191

A61M

(21) Int. Application Number: PCT/US91/09562	(51) International Patent Classification ⁵ : A61M 11/00	(11) Int. Publication Number: WO 92/11048
(22) Int. Filing Date: 18 December 1991 (18.12.91)	A1	(43) Int. Publication Date: 9 July 1992 (09.07.92)
(30) Priority data: 639,386 18 December 1990 US (18.12.90)	(54) Title: METERED DOSE INHALATION UNIT	
(71) Applicant: HEALTHSCAN PRODUCTS, INC. [US/US]; 908 Pompton Avenue, Unit B-2, Cedar Grove, NJ 07009-1292 (US).		
(72) Inventors: LARSON, Douglas, A.; 629 Ashland Avenue, River Forest, IL 60305 (US); DANOWSKI, Thomas, J.; 12 W. Remington, Schaumburg, IL 60195 (US).		
(74) Agent: BONDELL, Jay, A.; Schweizer Cornman & Gross, 230 Park Avenue, Suite 2200, New York, NY 10169 (US).		
(81) Designated States: AT (European patent), AU, BE (European patent), CA, CH (European patent), DE (European patent), DK (European patent), ES (European patent), FR (European patent), GB (European patent), GR (European patent), IT (European patent), JP, LU (European patent), MC (European patent), NL (European patent), SE (European patent).		
<p>Published</p> <p>With international search report.</p> <p>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</p>	<p>(57) Abstract</p> <p>An apparatus for dispensing a measured amount of a spray-entrapped product, typically dispensed by a metered dose inhaler device (20), includes an elongated passageway (12) having a mouthpiece portion (14) and a main chamber portion (16). The metered dose inhaler is mounted between the mouthpiece and main chamber portions such that upon operation its spray is directed away from the mouthpiece. A two-position valve (32) is provided to allow a first, low-level flow to be developed through the unit, followed by a higher flow rate as the metered dose inhaler unit is operated. This increased flow, passing through the device in the direction opposite to that of the MDI spray, contacts the spray plume to cause a high level of mixing and a decrease in spray particle size which results in an efficient draw of the spray medication into the lungs of the user.</p>	

(21) Int. Application Number: PCT/DK91/00400	(51) International Patent Classification ⁵ : A61M 11/06	(11) Int. Publication Number: WO 92/11049
(22) Int. Filing Date: 19 December 1991 (19.12.91)	A1	(43) Int. Publication Date: 9 July 1992 (09.07.92)
(30) Priority data: 3028/90 21 December 1990 DK (21.12.90)	(54) Title: A PEN SHAPED DEVICE FOR NASAL ADMINISTRATION OF DOSES OF A LIQUID MEDICINE	
(71) Applicant (for all designated States except US): NOVO NORDISK A/S [DK/DK]; Novo Allé, DK-2880 Bagsvaerd (DK).		
(72) Inventors; and (73) Inventors/Applicants (for US only): REX, Iorn [DK/DK]; Hyldeboer, 6, Gundersenvej, DK-4000 Roskilde (DK); STEENGAARD, Kim [DK/DK]; Kallistorg Allé 51, DK-2650 Hvidovre (DK); ELK, Svend [DK/DK]; Lyngboeghvej 48, DK-3460 Birkedal (DK).		
(74) Common Representative: NOVO NORDISK A/S; Patent Department, Novo Allé, DK-2880 Bagsvaerd (DK).		
<p>(81) Designated States: AT (European patent), AU, BE, BE (European patent), BF (OAPI patent), BG, BF (OAPI patent), BR, CA, CF (OAPI patent), CG (OAPI patent), CH (European patent), CI (OAPI patent), CM (OAPI patent), CS, DE (European patent), DK (European patent), ES (European patent), FI, FR (European patent), GA (OAPI patent), GB (European patent), GN (OAPI patent), GR (European patent), HU, IT (European patent), JP, KP, KR, LK, LU (European patent), MC (European patent), MG, ML (OAPI patent), MR (OAPI patent), MW, NL (European patent), NO, PL, RO, SD, SE (European patent), SM (OAPI patent), SU*, TD (OAPI patent), TO (OAPI patent), US.</p> <p>Published</p> <p>With international search report.</p>		

* See page 7124

Elias J. Lambiris Novo Nordisk of North America, Inc. 405 Lexington Avenue, Suite 6200 New York, New York 10017		UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) NOTIFICATION OF ACCEPTANCE OF APPLICATION UNDER 35 U.S.C. 371 AND 37 CFR 1.494 OR 1.495	
		Date of Mailing 18 AUG 1992	
		File Reference 3573.204-US	
IDENTIFICATION OF THE INTERNATIONAL APPLICATION			
International application Number	International filing date	Priority date claimed	
PCT/DK91/00400	December 19, 1991	December 21, 1990	
Applicant for DO/EO/US			
Jorn Rex; Kim Steengaard & Svend Elk			
NOTIFICATION			
The applicant is hereby advised that the United States Patent and Trademark Office in its capacity as a <input checked="" type="checkbox"/> Designated Office, <input type="checkbox"/> Elected Office, has determined that the above identified international application has met the requirements of 35 U.S.C. 371 and 37 CFR <input checked="" type="checkbox"/> 1.494, <input type="checkbox"/> 1.495 and is ACCEPTED for national patentability examination in the United States Patent and Trademark Office.			
The United States Serial Number assigned to the application and the relevant dates are: <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <u>01/793410</u> <u>1992</u> <u>18 AUG 1992</u> </div>			
U.S. NATIONAL SERIAL NO. 35 U.S.C. 102(e) DATE DATE OF RECEIPT 35 U.S.C. 371 REQUIREMENTS			
<input checked="" type="checkbox"/> A request for immediate examination under 35 U.S.C. 371 (f) was received on <u>18 AUG 1992</u> and the application will be examined in turn.			
<input type="checkbox"/> No request for immediate examination under 35 U.S.C. 371(f) was received. The application will not be processed or examined before the time limit set forth in either			
<input type="checkbox"/> PCT Article 23 (Chapter I of the PCT), or <input type="checkbox"/> PCT Article 40 (Chapter II of the PCT) whichever is applicable.			
UNITED STATES DESIGNATED/ ELECTED OFFICE			
ADDRESS ONLY: COMMISSIONER OF PATENTS AND TRADEMARKS Box PCT, Attn. DO/EO/US Washington, D.C. 20231		AUTHORIZED OFFICER <div style="text-align: right; margin-top: 20px;"> </div>	

Form PCT/DO/EO/903 (U.S. Version) (April 1987)

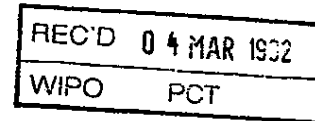
U.S. DEPARTMENT OF COMMERCE - PTO

28 Rec'd PCT/PTO

10 JUL 1976

PCT/GX 91/00400

#2 1/2



Kongeriget Danmark

PRIORITY DOCUMENT

Patent application No. : 3028/90
Date of filing: 21 Dec 1990
Applicant: Novo Nordisk A/S, Novo Alle, 2880 Bagsvaerd, DK
Int. Cl. 5: A 61M 5/00
Title of invention: Nose pen

This is to certify the correctness of the following information:

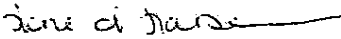
The attached photocopy is a true copy of the following documents:

- The specification, claims and drawings as filed with the application on the filing date indicated above.



 **Patentdirektoratet**

24 Jan 1992


Lene Nørregaard Larsen
Assistent

SAN00941640

1990-12-20 iit/DoJ

3573.000-DK

1

NOSE PEN

The invention concerns a dispensing device for dispensing dosed quantities of a fluid medicine as an aerosol appropriate to be assimilated through the nasal mucous membranes.

Many sorts of medicine are not appropriate for being orally consumed as they are destroyed very quickly in the alimentary canal. Such medicines, therefore, have to be injected to be directly assimilated in the blood.

10 When such medicines have to be taken frequently through a long period or even the life long as it is the case with e.g. insulin for diabetics, the wish for a method of taking the medicines without frequent injections occurs. Here the assimilation through the nasal mucous membranes is seen as
15 a solution.

From European Patent Application No. 308,100 is known a dispensing apparatus for dispensing metered quantities of pressurized fluid and in particular for nasal administration of insulin.

20 EP 308,100 meets the wishes for a device which may be used for nasal administration of e.g. insulin, as an activation of the device releases a metered quantity of liquid. However, the amount of liquid released by each activation is preset by the manufacturer of the spray valve, and if a bigger dose than
25 this preset one is wanted, the device must be activated repetitively until the wanted dose is dispensed.

The use of a propellant gas as in EP 308,100 is undesirable for more reasons. First of all, precaution should be taken to assure that the propellant gas is kept out of
30 contact with the medicine. Further, the content of sufficient propellant gas to dispense the total content of medicine involves the risk that an overdose is dispensed if the metering valve fails. Finally, as the device is intended to be disposed of when the medicine content is used up, it is against the time
35 spirit to use disposable devices containing propellant gases.

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Consequently, it is the object of the invention to provide a dispensing apparatus for nasal administration of medicine such as insulin in preset doses without the use of a propellant gas.

5 This is obtained by a device for nasal administration of a number of measured doses of a liquid medicine, especially insulin, comprising a first and a second housing element coupled together to allow rotation but no axial displacement of the first housing element with respect to the second housing
10 element, said first housing element comprising a carpule containing the liquid and being sealed by a piston at the end coupled to the second housing element and being at its other end closed by a valve to communicate the liquid in the carpule with a spray nozzle when opened, the device being characterized
15 according to the invention in that it further comprises a threaded piston rod engaging the piston of the carpule unrotably with respect to the first housing element and disposed in the second housing element to move axially therein, a nut element mounted unrotably but axially displaceably in the
20 second housing element engaging the thread of the piston rod, a helical spring abutting at its one end an internal annular abutment on the second housing element and at its other end a shoulder on the nut element to press this nut element and thereby the piston rod and the piston in the directions towards
25 the outlet end of the carpule setting the liquid therein under pressure to be released by opening the valve for spraying out a dose of the liquid, the housing elements, the rod, and the nut cooperating so that relative rotation between the housing elements in a selected direction causes relative rotation
30 between the rod and the nut element making the nut element move axially in the second housing element in a direction to compress the helical spring.

With the device according to the invention is further obtained a dispenser which will work in all positions and in
35 which the liquid remains sterile as no unclean air is to replace the liquid removed from the carpule during the spraying.

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According to the invention, the piston rod may be snap locked into the piston preventing a vacuum emerged in the carpule from drawing the piston into the carpule leaving an axial play between the piston rod and the piston.

5 To ensure that the liquid will hit the part of the nasal mucous membrane which is effective in assimilating the medicine, the nozzle is appropriately made to spray out the liquid at an angle of 0-30° defining the spray as ranging from a jet spray to a fan shaped spray.

10 The nut element may define at least one radially protruding axially extending projection on an exterior portion thereof, and this projection or these projections may be received in one or more corresponding axially extending groove or grooves in an inner portion of the second housing element
15 thereby providing a coupling between this housing element and the nut element ensuring that the nut element may be rotated with the second housing element and be axially displaced in this housing element.

A stop may be provided limiting the axial movement of
20 the nut element into the second housing element, thus limiting the loading of the device to a dose which surely may be assimilated through the nasal mucous membranes as it is of importance that the intended dose is actually assimilated.

Also the movement of the nut element along the piston
25 rod may be limited to avoid setting a larger dose than actually remains in the carpule.

In a preferred embodiment of the invention, the device has a removable protective cap configured to receive the first housing element and abutting when mounted thereon the
30 second housing element; and means for releasably coupling the protective cap and the first housing element for rotation together, so that rotation of the protective cap with respect to the second housing element causes rotation of the first housing element with respect to the second housing element.

35 The abutting edges of the second housing element and the protective cap may comprise pointing means and scale means, respectively, to measure the relative rotation of the protec-

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tive cap, and thereby the first housing element, with respect to the second housing element. The displacement of the nut element is proportional to this relative rotation and the measuring of the relative rotation consequently is a measuring 5 of the set dose.

Means may be provided for providing detents at selected rotational positions of the first housing element with respect to the second housing element making the extend of the relative rotation hearable and tactile as a click is heard and 10 a resistance variation is felt each time a detent is passed during the relative rotation.

The coupling means for coupling the protective cap to the first housing element may allow the protective cap to receive the first housing element in multiple different angular 15 positions of the protective cap with respect to the first housing element to allow the protective cap to be oriented at a selected position with respect to the second housing element, regardless of the detent rotational position of the first housing element in the second housing element. This way it is 20 always possible to mount the protective cap in position with the "0" of its scale in line with the pointing means on the second housing element.

By the abutting edges having interlocking means for defining a selected angular position of the protective cap with 25 respect to the second housing element it may be ensured that the cap is mounted in its 0-position when the pen is stored away after use. The interlocking means may appropriately comprise a recess on the abutting edge of the protective cap and a projection on the abutting edge of the second housing 30 element, the projection being shaped to fit into the recess to define the selected position.

In a preferred embodiment of the device according to the invention, the piston rod is made unrotably by fitting through an opening in an anti-rotation disc, the opening being 35 circular with at least one projection protruding into the opening, by the piston rod having a corresponding profile with recesses corresponding to the projections, and by the anti-

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rotary disc being at its periphery provided with alternating spaces and teeth fitting into a castellated end of the first housing element. Further, the anti-rotary disc serves as an abutment for the nut element limiting the movement of this 5 element towards the carpule.

The abutting faces of the nut element and the anti-rotary disc are shaped as annular ramps which when in mutual abutment allow only relative rotation of the first and second housing elements in a device loading direction. Thereby it is 10 precluded that a relative rotation in a direction to unload the device to annul a set dose is continued when the device is unloaded. Such a continued relative rotation could draw the piston rod free of the piston and provide an axial play which would undermine the correct dosing.

15 In a preferred embodiment, the nut element may have a tubular extension coaxially surrounding the piston rod and terminated by a knob at the outer end of the second housing element, this knob being flush with the edge of this outer end, when the annular ramps of the anti-rotary disc and the nut 20 member are in a mutual abutment giving a tactile indication whether the device is loaded or not.

In the following the invention is specified in further detail with reference to the drawing in which

- 25 Fig. 1 shows a plan view of a dispenser according to the invention,
- Fig. 2 shows a plan view of the protective cap,
- Fig. 3 shows a sectional view along the line III-III in Fig. 1, but without the piston rod,
- 30 Fig. 4 shows an enlarged plan view of the anti-rotary disc,
- Fig. 5 shows a side view of the disc in Fig. 4.
- Fig. 6 shows an enlarged detail of the abutting edges of the protective cap and the second housing element in dose setting position, and
- 35 Fig. 7 shows the detail of Fig. 6 in closed position for storing.

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Fig. 1 shows a pen shaped device having a first housing element 1 and a second housing element 2 snapped together by an external bead 3, and the first housing element 1 being snapped into an annular groove 4 in the second housing element 2 permitting the two housing elements to be rotated in relation to each other about the common length axis, but not to be displaced in relation to each other along this axis.

The first housing element 1 forms a carpule for a liquid medicine and is at its one end provided with a neck 10 forming a valve chamber 5 communicating at its one end with the housing element and being at its other end closed by a valve block 6 fitting into an annular sealing 7 fitted to the valve chamber 5 by a ferrule 8. The valve block has radial ducts 9 leading to a central bore 10 and being at the outer ends sealed 15 by the inner cylindric surface of the annular sealing 7 when the valve is closed. An inner element 11 of a spray nozzle has a rod fitting into the bore 10 with a small clearance leaving a duct leading to a spray nozzle 12 in a nozzle element 13 surrounding the inner element 11 leaving a fine duct from the 20 bore 10 to the nozzle 12.

The nozzle element 13 is provided with a tubular central part 14 fitting over the part with the bore 10. An internal annular bead 15 in the part 14 is lodged in an annular groove 16 in the part with the central bore.

25 The nozzle element 13 further comprises a shirt 17 surrounding at some distance the tubular central part 14 and being at its edge snapped on the neck 18 of a release member 19 fitting over the outer end of the carpule, the neck 18 of the release member 19 being so much shorter than the neck of the 30 carpule that it may be axially displaced along the neck of the carpule limited by its outer end abutting the ferrule or by its shoulder abutting the shoulder of the carpule.

The nozzle element and the release member 19 is kept in its position with the neck 18 of the release member 19 35 abutting the ferrule 8 by a helical spring 20 surrounding the central part 14 of the nozzle element 13 abutting at its one end the ferrule 8 and at its other end a contact face between

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the central part 14 and the skirt 17 of the nozzle element 13. In this position the radial ducts 9 lie opposite the sealing 7 and the valve is closed. When the release member 19 is displaced in its axial direction to bring its internal shoulders 5 in abutment with the outer shoulders of the carpule, the radial ducts 9 are passed past the sealing 7 and into the valve chamber 5 and a communication between the liquid in the carpule is established through the chamber 5, the radial ducts 9, the bore 10 and the clearance between the inner element 11 and the 10 nozzle element 13 to the spray nozzle 12. This way the liquid in the carpule will be sprayed out through the nozzle 12 when set under pressure as described below.

The pressure in the carpule is provided by pressing a piston 21 closing the end of the carpule opposite the neck 15 into the carpule. An O-ring is mounted in a circumferential groove in the piston to provide a sealing between the piston and the carpule wall.

A piston rod 22 engaging the piston 21 protrudes through an anti rotary disc 23 mounted at the end of the first 20 housing element 1 to make the piston rod unrotably in relation to this housing element.

This may be obtained by the disc, as shown in Figs. 4 and 5 having spaced teeth 42 along its periphery fitting into a castellated end of the first housing element and by the 25 piston rod having a non-circular profile fitting into a corresponding central opening in the disc. The piston rod is a mainly cylindric, threaded rod having diametrically opposite axial recesses 25 engaged by corresponding diametrically opposite projections 26 in the mainly circular opening of the 30 anti-rotary disc.

The mainly cylindric piston rod 22 is threaded and is surrounded by a nut element 27 having at its end facing and abutting the anti-rotary disc a short internal thread 28, the rest of the inner surface of the nut element 27 being smooth 35 fitting over the threaded piston rod to guide this rod in its axial movement. The nut element has at its threaded end external axial ribs 29 engaging internal axial grooves in the

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second housing element 2 making the nut element 27 inrotably, but axially displaceable in this housing element.

The grooves in the second housing element are each defined by pairs of spaced internal projections 30 in the 5 second housing element. Together with the ribs 29 ending in a plate 41 at the end abutting the anti-rotary disc the projections 30 define a stop for the movement of the nut element as the plate 41 fits closely into the circular bore of the second housing element and consequently will abut the ends of the 10 projections 30 when the nut element is displaced into the second housing element. Thereby the maximal loading of the device is limited.

When the piston rod 22 is rotated relative to the nut element 27 in one direction by rotating the first housing 15 element relative to the second housing element the nut element is moved away from its abutment 31 on the anti-rotary disc 23 and is displaced further into the second housing element compressing a helical spring 32 abutting at its one end the nut element and at its other end an annular protrusion on the inner 20 surface of the tubular second housing element. The compressed spring 32 will try to press the nut element back to abut the disc 23, and this force exerted on the nut member will be transmitted to the piston rod and the piston through the threads in the nut element on the piston rod, thereby setting 25 the content of the carpule under pressure. This pressure may be released by operating the valve to spray out the preselected dose of the medicine in the carpule. During this spraying the piston is moved into the carpule until the nut member abuts the disc 23 again.

30 At its end opposite the piston the piston rod is provided with a head 40 limiting the movement of the nut element along the piston rod to assure that a dose exceeding the remaining liquid in the carpule may not be preset.

The engagement between the piston rod 22 and the 35 piston 21 is performed as a snap lock. This way the piston 22 may be driven into the carpule by the piston rod 22, the snap

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lock connection being flexible to permit the piston to follow marginal volume variations caused by temperature variations.

The loading of the device by turning the housing elements 1 and 2 in one direction relative to each other may also be annulled by rotating the two housing elements in the opposite direction relative to each other until the nut element is displaced to abut the disc again. The mutually abutting surfaces of the nut element and the disc 23 are provided with respective ramps to prevent further relative rotation in this direction when the nut member abuts the disc. This way it is prevented that a further relative rotation of the housing elements in this direction will cause the piston rod to be drawn out of engagement with the piston.

The end of the tubular nut element opposite the disc 15 is provided with a knob 33 having an outer cylindric surface fitting guidingly into the bore of the tubular second housing element and an end surface flush with the end edge of the second housing element when the device is not loaded. When the device is loaded and the nut element is displaced away from the disc, the knob is protruding from the end of the second housing element giving a tactile information of the status of the device, i.e. whether the device is loaded or not.

The spray nozzle element 13 is covered by a cap 34 when the device is not in use. This cap is provided with a clip 35, so that it can be carried in a pocket like a fountain pen. The cap 34 fits over the first housing element 1 and when fitted on is adjacent to and flush with the second housing element 2. The adjacent edges of the second housing element 2 and the cap 34 are provided with a projection 38 and a corresponding recess 39, respectively, the projection engaging the depression when the cap is fitted on.

The cap is provided with internal grooves 36 engaged by external ribs 37 on the first housing element 1. Thereby the cap can be used for rotating the first housing element 1 relative to the second housing element 2 when the cap is appropriately axially displaced on the first housing element to bring the projection 38 out of engagement with the recess 39.

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The projection 39 is made as an arrow pointing on a scale on the cap, so that a dosing measured in units may be set by the turning of the two housing elements relative to each other. The rotatable connection between the two housing elements is provided with a click mechanism providing a hearable and perceptible click at each two units set.

When the dose is set, the cap is removed from the device and the nozzle element is inserted in a nostril, and the release member 19 is pulled further over the first housing element to release the dose which is sprayed out through the nozzle at an angle of 0-30°. After use the cap is again fitted over the first housing element in a rotary position making the projection 38 engage the depression 39.

The first housing element forming the carpule is made of a transparent plastic allowing the position of the piston to be observed to decide how much liquid is left. For this purpose the first housing element may be provided with a scale. When the carpule is empty, the device may be disposed of.

Although the device is described with the carpule forming an integral part of the first housing element, an embodiment wherein a separate carpule is received in the first housing element will be within the scope of the invention.

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CLAIMS

1. A device for nasal administration of a number of measured doses of a liquid medicine, especially insulin, comprising a first and a second housing element coupled together to allow rotation but no axial displacement of the first housing element with respect to the second housing element, said first housing element comprising a carpule containing the liquid and being sealed by a piston at the end coupled to the second housing element and being at its other end closed by a valve to communicate the liquid in the carpule with a spray nozzle when opened, characterized in that the device further comprises a threaded piston rod engaging the piston of the carpule unrotably with respect to the first housing element and disposed in the second housing element to move axially therein, a nut element mounted unrotably but axially displaceably in the second housing element engaging the thread of the piston rod, a helical spring abutting at its one end an internal annular abutment on the second housing element and at its other end a shoulder on the nut element to press this nut element and thereby the piston rod and the piston in the directions towards the outlet end of the carpule setting the liquid therein under pressure to be released by opening the valve for spraying out a dose of the liquid, the housing element, the rod, and the nut cooperating so that relative rotation between the housing elements in a selected direction causes relative rotation between the rod and the nut element making the nut element move axially in the second housing element in a direction to compress the helical spring.

2. A device according to claim 1, characterized in that the piston rod is snap locked into the piston.

3. A device according to claim 1 or 2, characterized in that the nozzle sprays out the liquid at an angle of 0-30°.

4. A device according to any of the preceding claims, characterized in that the nut element defines at least one radially protruding, axially extending projection on an exterior portion thereof; and the projection is received in an

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axially extending groove in an inner portion of the second housing element.

5. A device according to any of the preceding claims, characterized in that a stop is provided limiting axial movement of the nut element into the second housing element.

6. A device according to any of the preceding claims, characterized in that a stop is provided limiting the movement of the nut element along the piston rod.

7. A device according to any of the preceding claims, characterized in that it has a removable protective cap configured to receive the first housing element and abutting when mounted thereon the second housing element; and means for releasably coupling the protective cap and the first housing element for rotation together, so that rotation of the protective cap with respect to the second housing element causes rotation of the first housing element with respect to the second housing element.

8. A device according to claim 7, characterized in that the abutting edges of the second housing element and the protective cap comprise pointing means and scale means, respectively, to measure the relative rotation of the protective cap with respect to the second housing element.

9. A device according to claim 8, characterized in that means are provided for providing detents at selected rotational positions of the first housing element with respect to the second housing element.

10. A device according to claim 9, characterized in that the coupling means allow the protective cap to receive the first housing element in multiple different angular positions of the protective cap with respect to the first housing element to allow the protective cap to be oriented at a selected position with respect to the second housing element, regardless of the detent rotational position of the first housing element in the second housing element.

11. A device according to claim 9, characterized in that the abutting edges have interlocking means for defining a

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selected angular position of the protective cap with respect to the second housing element.

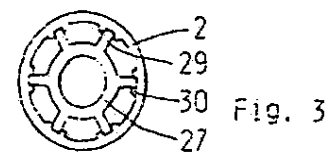
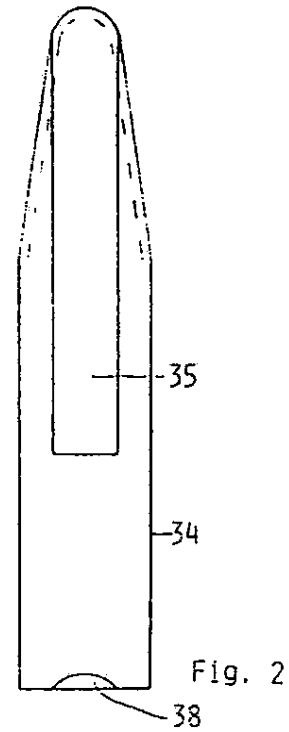
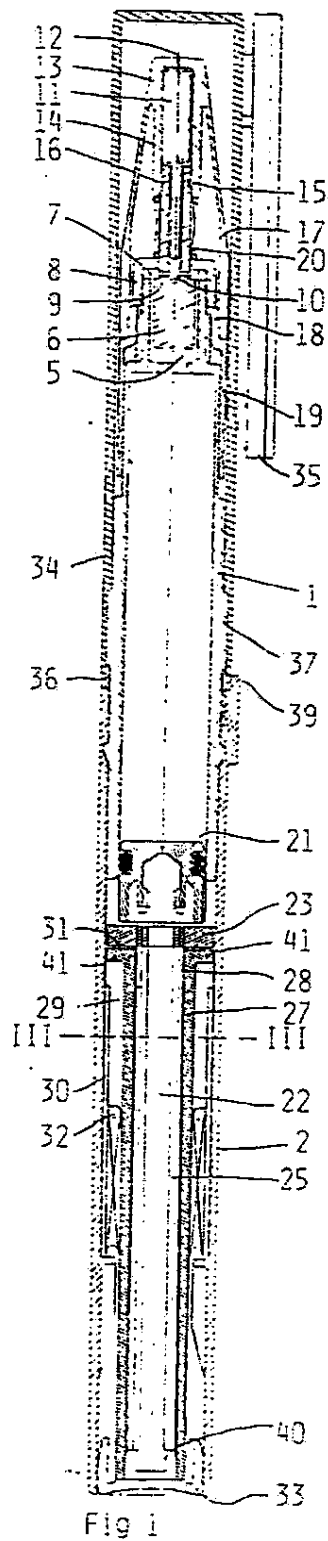
12. A device according to claim 10, characterized in that the interlocking means comprise a recess on the abutting
5 edge of the protective cap and a projection on the abutting edge of the second housing element, the projection being shaped to fit into the recess to define the selected position.

13. A device according to any of the preceding claims, characterized in that the piston rod is made in-
10 rotatable with respect to the first housing element by fitting through an opening in an anti-rotation disc, the opening being mainly circular with at least one projection protruding into the opening, by the piston rod having a corresponding profile with recesses corresponding to the projections, and by the
15 anti-rotary disc being at its periphery provided with alternating spaces and teeth fitting into a castellated end of the first housing element.

14. A device according to claim 13, characterized in that the anti-rotary disc serves as an abutment for the nut
20 element limiting its movement towards the carpule.

15. A device according to claim 13, characterized in that the abutting faces of the nut element and the anti-rotary disc are formed as annular ramps which when in mutual abutment
allow only relative rotation of the first and second housing
25 element in a device loading direction.

16. A device according to claims 14, characterized in that the nut element has an tubular extension coaxially surrounding the piston rod and terminated by a knob at the outer end of the second housing element, this knob being flush
30 with the edge of this outer end when the annular ramps of the anti-rotary disc and the nut member are in mutual abutment.



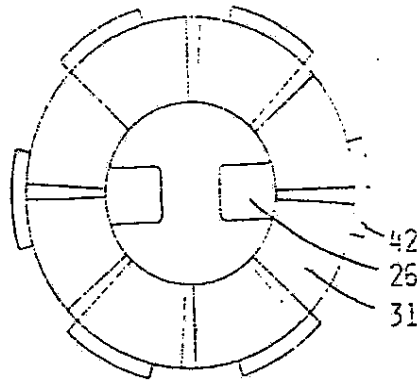


Fig. 4

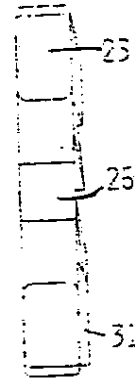


Fig. 5

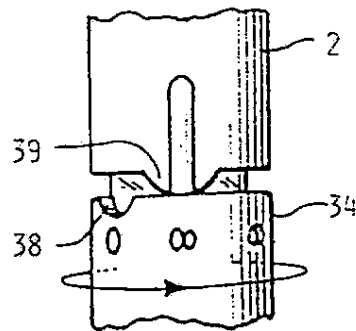


Fig. 6

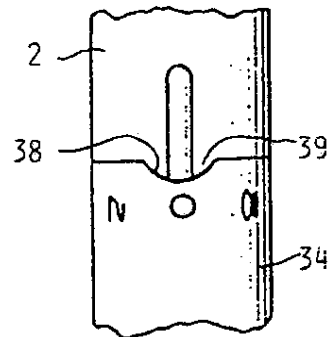


Fig. 7



Attorney Docket No.: 3573.204-US

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L. Park
10-9-92
#3/Prior art

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Rex et al.

Serial No.: 07/793,412

Group Art Unit: 3104

Filed: January 13, 1992

Examiner: to be assigned

For: NOSE PEN

CERTIFICATE OF MAILING UNDER 37 CFR 1.8(a)

Hon. Commissioner of Patents and Trademarks
Washington, DC 20231

Sir:

I hereby certify that the attached correspondence
comprising:

1. Information Disclosure Statement
2. PTO-1449 Form
3. Copy of References

is being deposited with the United States Postal Service as
first class mail in an envelope addressed to:

Commissioner of Patents and Trademarks
Washington, DC 20231

on August 28, 1992.

Elias J. Lambiris
(name of person mailing paper)

Elias J. Lambiris
(signature of person mailing paper)



Attorney Docket No.: 3573.204-US

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SEP -3 PATENT

GROUP 310

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Rex et al.

Serial No.: 07/793,412 Group Art Unit: 3104

Filed: January 13, 1992 Examiner: to be assigned

For: NOSE PEN

INFORMATION DISCLOSURE STATEMENT

Hon. Commissioner of Patents and Trademarks
Washington, DC 20231

Sir:

In accordance with 37 C.F.R. 1.56, 1.97 and 1.98, Applicants submit herewith references which they believe may be material to the examination of this application and with respect to which there may be a duty to disclose in accordance with 37 C.F.R. 1.56.

While the references may be "material" under 37 C.F.R. 1.56, it is not intended to constitute an admission that the references are "prior art" unless specifically designated as such.

In accordance with 37 C.F.R. 1.97(b), the filing of this Information Disclosure Statement shall not be construed as a representation that no other material references than those listed exist or that a search has been conducted.

The references are listed in PTO form 1449 which is in accordance with the requirements of M.P.E.P. 609. A copy of the references is also enclosed.


The references are as follows:

1. U.S. Patent 4,962,868
2. Published Great Britain Patent Application
1,379,688
3. Published European Patent Application 0 308 100
and
4. Published PCT Patent Application WO 91/15303.


It is respectfully requested that these references be considered by the Patent and Trademark Office in its examination of the above-identified application and be made of record therein. The Examiner is also invited to contact the Undersigned if there are any questions concerning this paper or the attached references.

Respectfully submitted,

Date: August 28, 1992


Elias J. Lambiris, Reg. No. 33,728
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405 Lexington Avenue, Suite 6200
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(212) 867-0123

FWC 08/054913 Sheet 1 of 1

FORM PTO-1449 (Rev. 2-32)  INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	Atty. Docket No. 3573.204-US	Serial # RECEIVED #3 07/793,412
	Applicant Rex et al.	Filing Date January 13, 1992	1992 SEP -3 AM 11:13 Group 310 3104 3307

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
<i>KA</i>	4,962,868	10/16/90	H. J. Borchard	222	49	04/21/89

FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
<i>KA</i>	GB 1 379 688	01/08/75	Great Britain				
<i>KA</i>	EP 0 308 100	03/22/89	Europe				
<i>KA</i>	WO 91/15303	10/17/91	PCT				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

EXAMINER

KA

DATE CONSIDERED

11/5/92

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.


UNITED STATES DEPARTMENT OF COMMERCE
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07/793412

07/793412 01/13/92 REV

J 3570, 204-08

EXAMINED

ASHER, K.

AMOUNT PAPER NUMBER

3307

4

DATE MAILED 12/01/92

 STEVE L. ZELSON
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 NEW YORK, NY 10017

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

 A shortened statutory period for response to this action is set to expire 2 month(s), _____ days from the date of this letter.
 Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133
Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited by Examiner, PTO-692. | 2. <input checked="" type="checkbox"/> Notice re Patent Drawing, PTO-948. |
| 3. <input checked="" type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of informal Patent Application, Form PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-10 are pending in the application.
 Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☒ Claims 1-3 are allowed.
4. ☐ Claims _____ are rejected.
5. ☒ Claims 4-10 are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with Informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable, ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner, ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved, ☐ disapproved (see explanation).
12. ☒ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☒ been received ☐ not been received
☐ been filed in parent application; serial no. _____; filed on _____
13. ☒ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

PTOL-326 (Rev. 9-89)

SAN00941660

07/793,412
ART UNIT 337

This application is in condition for allowance except for the following formal matters:

- 5 a) the specification and claims must be amended so as to be
 in proper idiomatic English and to correct minor
 errors. Examples of such are found on page 1, line 25,
 "time spirit"; page 2, line 3, "0 C0"; page 8,
 paragraph 3, "piston 22" and "piston rod 22" (what are
10 the proper reference numerals?); and throughout the
 application, "unrotatable". These are examples only,
 the entire application must be corrected.
- b) the Declaration is defective because Mr. Rex did not
 provide a complete date, i.e. the year is missing. As
15 the Declaration can not be amended, a new Declaration
 is required which acknowledges all amendments.
- c) a proper abstract is required for the Printer on a
 separate sheet of paper.
- d) claims 4-16 are not in proper U.S. multiple dependent
20 claim format. Appropriate amendment of these claims
 into proper U.S. form is required. Applicants' are
 respectfully reminded that additional fees will be
 required if the claims are put into proper U.S.
 multiple dependent claim format, as applicants were
25 only charged previously for multiple dependent claim 3.
 The claims are improper multiple dependent claims

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ART UNIT 337

because they depend upon other multiple dependent claims.

e) In claim 1, line 17, note "directions"; in claim 1, line 18, it is suggested that --of-- be added before "the", and that "coupled" in line 3 be replaced with --and means coupling said housing elements-- to improve claim clarity; in claim 16, line 1, note "claims 14".

10 Prosecution on the merits is closed in accordance with the practice under ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.

15 A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS ACTION IS SET TO EXPIRE TWO MONTHS FROM THE DATE OF THIS LETTER.

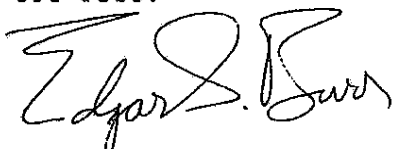
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

20 Turner et al teach a dose metering dispenser comprising a threaded plunger and spring arrangement. Holm et al teach a great deal of applicants' claimed invention, but lack the valve, spring, and a spray nozzle. Jessup teaches a syringe sprayer. The remaining references all teach dispensers in the form of pens which deliver metered doses by injection, not by spraying.

30 An inquiry concerning this communication should be directed to K. L. Asher at telephone number (703) 308-0858.

35 K. L. Asher
November 12, 1992

3


EDGAR S. BURR
S.P.E.
GROUP ART UNIT 337

SAN00941662

TO SEPARATE, HOLD TOP AND BOTTOM EDGES, SNAP-APART AND DISCARD CARBON

FORM PTO-892 (REV. 2-92)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		SERIAL NO. <u>08/054913</u> <u>67793412</u>		GROUP ART UNIT <u>3307</u>		ATTACHMENT TO PAPER NUMBER <u>4</u>	
NOTICE OF REFERENCES CITED				APPLICANT(S): <u>Rev et al</u>					
U.S. PATENT DOCUMENTS									
		DOCUMENT NO.		DATE	NAME	CLASS	SUB-CLASS	FILING DATE IF APPROPRIATE	
A	4	4	05308	9/1983	Gessup	128	300.22		
B	5	0	17190	5/1991	Simon et al	604	209	4/7/89	
C	4	4	13760	11/1983	Paton	604	209		
D	5	1	12317	5/1992	Michel	604	232	1/18/89	
E	5	1	14406	5/1992	Gabriel et al	604	232	11/10/87	
F	5	1	04380	4/1992	Holman et al	604	232	4/18/89	
G	4	9	73314	11/1990	Holm et al	604	211	2/9/89	
H	4	4	98904	2/1985	Jurmer et al	604	211		
I									
J									
K									
FOREIGN PATENT DOCUMENTS									
		DOCUMENT NO.		DATE	COUNTRY	NAME	CLASS	SUB-CLASS	PERTINENT SHYS. DWG. SPEC.
L									
M									
N									
O									
P									
Q									
OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)									
R									
S									
T									
U									
EXAMINER <u>Ascher</u>				DATE <u>11/6/92</u>					
* A copy of this reference is not being furnished with this office action. (See Manual of Patent Examining Procedure, section 707.05 (a).)									

PTO FORM 940
(Rev. 1-87)U.S. DEPARTMENT OF COMMERCE
Patent and Trademark Office

ATTACHMENT TO PAPER NUMBER

APPLICATION NUMBER

3300

NOTICE OF DRAFTSMAN'S PATENT DRAWING REVIEW

The PTO Draftsman review all originally filed drawings regardless of whether they were designated as informal or formal.

The drawings filed

A. ☒ are approvedB. ☐ are rejected in whole or in part for reason(s) checked below. The applicant will require submission of new, corrected drawings at the appropriate time. Corrected drawings must be submitted according to the instructions listed in the back of this Notice.

1. Paper and Size. 37 CFR 1.84(a)

☐ Conventional Paper. Must Be 4-1/2" x 6-1/2"

Furnished Paper Not Allowed.

Folding _____

2. Order of Sheet and Margins. 37 CFR 1.84(b)

Compatible Paper Sizes and Margins

Paper Size

Margin	8 1/2 by 14 inches	8 1/2 by 13 inches	JIN size A4 21 by 29.7 cm.
Top	2 inches	1 inch	2.5 cm.
Left	1/4 inch	1/4 inch	2.5 cm.
Right	1/4 inch	1/4 inch	1.5 cm.
Bottom	1/4 inch	1/4 inch	1.0 cm.

☐ Proper Size Paper Required. All

Sheets Must be Same Size.

Sheet(s) _____

☐ Proper Margins Required.

Sheet(s) _____

☐ Top ☐ Right
☐ Left ☐ Bottom

3. Character of Lines. 37 CFR 1.84(c)

☐ Lines Pale, Rough and Blurred, or Jagged. Fig(s) _____☐ Solid Black Shading Not Allowed. Fig(s) _____4. ☐ Photographs Not Approved.☐ Comments:

5. Hatching and Shading. 37 CFR 1.84(d)

☐ Shade Lines are Required.

Fig(s) _____

☐ Cross-Cross Hatching Not Allowed.

Fig(s) _____

☐ Double Line Hatching Not Allowed.

Fig(s) _____

☐ Parts in Section Must be Hatched Properly. Fig(s) _____

6. Reference Characters. 37 CFR 1.84(f)

☐ Reference Characters Poor or Rough and Blurred. Fig(s) _____☐ Minimum 1/8 inch (3.2 mm.) in height is required. Fig(s) _____☐ Figure Legends Poor or Placed Incorrectly. Fig(s) _____

7. Views. 37 CFR 1.84(i) - 3 (j)

☐ Figures Must be Numbered Separately.☐ Figures Must Not be Connected. Fig(s) _____

8. Identification of Drawings. 37 CFR 1.84(i)

☐ Extraneous Matter or Copy Machine Marks Not Allowed. Fig(s) _____☐ Changes Not Completed from Prior PTO-948 dated _____

Telephone inquiries concerning this review should be directed to the Chief Draftsman at telephone number (703) 557-6404.

Reviewing Draftsman

Date

PTO Copy

SAN00941664

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities—37 CFR 1.85

File new drawings with the changes incorporated therein. The art unit number, serial number and number of drawing sheets should be written on the drawings in accordance with 37 CFR 1.84(i). Applicant may delay filing of the new drawings until receipt of the "Notice of Allowability" (PTOL-37). If delayed, the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period for response in the "Notice of Allowability" (PTOL-37). Extensions of time may be obtained under the provisions of 37 CFR 1.104. The drawing should be filed as a separate paper with a transmittal letter addressed to the Official Draftsman.

Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the three month shortened statutory period in the "Notice of Allowability" (PTOL-37). Within that three month period, two weeks should be allowed for review by the Office of the Examiner. If a correction is determined to be unacceptable by the Office, applicant must arrange to have acceptable correction re-submitted within the original three month period to avoid the necessity of obtaining an extension of time and paying the extension fee. Therefore, applicant should file corrected drawings as soon as possible.

Failure to take corrective action within set (or extended) period will result in **ABANDONMENT** of the Application.

2. Corrections other than Informalities Noted by the Draftsman on the PTO-946

All changes to the drawings, other than informalities noted by the Draftsman, **MUST** be made in the same manner as above except that, normally, a red ink sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

07/793412

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
07/793 412	01/13/92	REF	1 3573,204-US

STEVE T. ZELSON
NOVO NORDISK OF NORTH AMERICA, INC.
405 LEXINGTON AVE.,
SUITE 6200
NEW YORK, NY 10017

EXAMINER	
ASHER, K	
ART UNIT	PAPER NUMBER
3307	5

DATE MAILED:

EXAMINER INTERVIEW SUMMARY RECORD

02/05/93

All participants (applicant, applicant's representative, PTO personnel):

- (1) Mr. Steve Zelson (# 30,335) (3) _____
(2) Ex. Asher (4) _____

Date of interview Feb. 4, 1993

Type: ☒ Telephonic ☐ Personal (copy is given to ☐ applicant ☐ applicant's representative).

Exhibit shown or demonstration conducted: ☐ Yes ☒ No. If yes, brief description: _____

Agreement ☐ was reached with respect to some or all of the claims in question. ☒ was not reached.

Claims discussed: n/a

Identification of prior art discussed: n/a

Description of the general nature of what was agreed to if an agreement was reached, or any other comments: The requirement for a new declaration was discussed. A new Declaration is necessary due to the lack of a dated signature for George Fox. If any amendments are filed prior to filing of the new Declaration, the Decl. must acknowledge the amendments - 37 CFR 1.63 (b)(1).

(A fuller description, if necessary, and a copy of the amendments, if available, which the examiner agreed would render the claims allowable must be attached. Also, where no copy of the amendments which would render the claims allowable is available, a summary thereof must be attached.)

Unless the paragraphs below have been checked to indicate to the contrary, A FORMAL WRITTEN RESPONSE TO THE LAST OFFICE ACTION IS NOT WAIVED AND MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW (e.g., items 1-7 on the reverse side of this form). If a response to the last Office action has already been filed, then applicant is given one month from this interview date to provide a statement of the substance of the interview.

☐ It is not necessary for applicant to provide a separate record of the substance of the interview.

☐ Since the examiner's interview summary above (including any attachments) reflects a complete response to each of the objections, rejections and requirements that may be present in the last Office action, and since the claims are now allowable, this completed form is considered to fulfill the response requirements of the last Office action.

Kimberly L. Asher
Examiner's Signature

PTOL-413 (REV. 1-84)

ORIGINAL FOR INSERTION IN RIGHT HAND FLAP OF FILE WRAPPER

SAN00941666



Attorney Docket No.: 3573.204-US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Rex et al.

Serial No.: 07/793,412

Group Art Unit: 3307

Filed: January 13, 1992

Examiner: K. Asher

For: NOSE PEN

TRANSMITTAL OF SUPPLEMENTAL DECLARATION

Hon. Commissioner of Patents and Trademarks
Washington, DC 20231

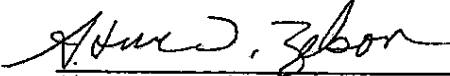
Sir:

Applicants' enclose herewith a fully executed,
Supplemental Declaration.

The Examiner is hereby invited to contact the
undersigned by telephone if there are any questions concerning
this application.

Respectfully submitted,

Date: March 16, 1993


Steve T. Zelson, Reg. No. 30,335
Novo Nordisk of North America, Inc.
405 Lexington Avenue, Suite 6200
New York, NY 10174-6201
(212) 867-0123

L. Spruell
3-30-93
#6/
Lt.
+ *Supl.*
Decl.